SPECIAL USE PERMIT

Planning Office – 600 9th Street – Wheatland, Wyoming 82201
Office 307.322-2962 – Fax 307.322.2968

All applications must include the following:

- □ **Application:** Fill out the application form completely. *Incomplete applications will be returned.*
- □ **Fees:** All applicable fees. Check or Cash only, the planning office cannot process credit cards.
- □ **Site Plan:** Complete site plan
- □ **Project Plan:** Engineer and/or design drawings and information, if applicable.
- □ **Proof of Ownership:** Book and page number of the deed, copy of the deed, lease, or contract for purchase.
- □ **Letter of Justification:** Statement of purpose/intent.
- □ **Parking Plan:** Commercial, Industrial, and Multi-Family parcels are required to provide a parking plan, if applicable.

IMPORTANT NOTICES

- ❖ Special Use of Property applications must be heard at public hearings by both the Platte County Planning and Zoning Commission and Platte County Board of Commissioners.
- ❖ Special Use of Property applications must be approved by the Platte County Board of Commissioners **before** the use specified within the application can begin.
- ❖ The applicant agrees to abide by the Platte County Planning and Zoning Rules and Regulations, as well as any requirements and/or conditions specific to the property required by Platte County.
- ❖ Additional application requirements can vary depending on the zoning of the property.

SPECIAL USE OF PROPERTY

Applicant Name: _____ Phone No.: _____

Mailing Address: _____

E-mail Address: _____

If the applicant is other than the owner of the property for which this special use permit is being sought, the applicant must provide separate written approval from the owner, or the owner may indicate approval by signing below.

Owner Name: _____ Signature.: _____

Mailing Address: _____

E-mail Address: _____ Phone No.: _____

Proof of Ownership: Deed Book _____ Page _____, □ Deed, Lease, Purchase Contract Attached

SUP-____-____

Physical address of property for which this special use permit is being requested:

_____

Legal description of property for which this Special Use Permit is being requested:

Subdivision: _____ Tract/Lot(s): _____ Quarter Section: _____

Of Section: _____ Township _____ North, Range _____ West

Acreage: _____ Located within a floodplain: □ Yes □ No

Current Land Use: _____ Zoning Classification: _____

Proposed use of property. **for animals, include: type, number, and use of animals, (i.e.: pet, grazing, breeding, other; square footage of property; plot plan indicating location and size of all buildings, including animal shelter(s), fencing, and information relating to the type of shelter provided) **Other uses include: size of building(s), number of occupants and/or employees, hours of operation, and a site plan: _____

_____

_____

_____

SITE PLAN REQUIREMENTS

- Show the entire lot or parcel with dimensions and orient the drawing with the North Arrow.
- Indicate adjacent roads and their names.
- Indicate locations and outside dimensions of all buildings.
- Setbacks are required for buildings and/or project structures. Indicate setbacks from property lines, easements, rights-of-way, and roads for all proposed structures and provide the distances.
- Setbacks are required for both the well and wastewater (septic) system. Indicate setbacks from property lines with distances to well and wastewater system.
- Indicate other significant features or improvements of the subject property, such as streams, ponds, irrigation ditches, pipelines, wells, floodplains, wastewater systems, corrals, fence/screening, towers, overhead power lines, etc.
- Commercial, Industrial, and Multi-Family parcels must identify landscaping and parking areas.
- Indicate the driveway location(s), off-street parking, and routes of ingress and egress.

APPLICATION SIGNATURE(S) AND ACCESS PERMISSION

Right to ingress property for assessment, evaluation, and inspections.

I, the undersigned, hereby grant authorized Platte County Personnel the right to enter onto this said land/property for all inspection, assessment, and/or evaluation purposes necessary to exercise this Special Use Permit. I certify, to the best of my knowledge, that all the information in this application is true and correct, and that I am the owner of the above-described property or have been authorized by the owner to make this application as his/her agent.

_____ _____

Signature of Applicant(s) Date

PLANNING OFFICE USE ONLY

Date completed application received: _____ Application Fee Total: _____

Planning & Zoning Commission Public Hearing Date: _____ Approved □ Disapproval □

Board of County Commissioners Public Hearing Date: _____ Approved □ Disapproval □

This Special Use Permit request is granted □ with/□ without conditions; this _____ day of _____, 2021.

_____

County Commissioner Chairman

Special Use Permit Conditions: _____

_____

_____

REZONE APPLICATION

Planning Office – 600 9th Street – Wheatland, Wyoming 82201
Office 307.322-2962 – Fax 307.322.2968

Platte County
PLANNING & ZONING

All applications must include the following:

- □ **Application:** Fill out the application form completely. *Incomplete applications will be returned.*
- □ **Fees:** All applicable fees. Check or Cash only, the planning office cannot process credit cards.
- □ **Site Plan:** Complete site plan and/or plat (PDF preferred)
- □ **Proof of Ownership:** Book and page number of the deed, copy of the deed, lease, or contract for purchase.
- □ **Letter of Justification:** Statement of purpose and/or need for the rezone.
- □ **Parcel Boundary Map:** Map showing the surrounding area and boundary of the parcel of the proposed rezone area.

Applicant Name: _____ Phone No.: _____

Mailing Address: _____

E-mail Address: _____

If the applicant is other than the owner of the property for which this rezone is being sought, the applicant must provide separate written approval from the owner, or the owner may indicate approval by signing below.

Owner Name: _____ Signature.: _____

Mailing Address: _____

E-mail Address: _____ Phone No.: _____

Proof of Ownership: Deed Book _____ Page _____, □ Deed, Lease, Purchase Contract Attached

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Legal description of property for which this rezone is being requested:

Subdivision: _____ Tract/Lot(s): _____ Quarter Section: _____

Of Section: _____ Township _____ North, Range _____ West

Legal description can be found on the property deed.

Located within the Wheatland Irrigation District Boundaries: □ Yes □ No

If yes, attach the corresponding approved Wheatland Irrigation District Water Plan for Subdividers.

Current Land Use: _____ Current Zoning Class: _____

Proposed Land Use: _____ Requested Zoning Class: _____

R-____-____

SITE PLAN REQUIREMENTS

- Show the entire lot or parcel with dimensions and orient the drawing with the North Arrow.
- Indicate adjacent roads and their names.
- Indicate locations and outside dimensions of all buildings.
- Setbacks are required for buildings and/or project structures. Indicate setbacks from property lines, easements, rights-of-way, and roads for all proposed structures and provide the distances.
- Setbacks are required for both the well and wastewater (septic) system. Indicate setbacks from property lines with distances to well and wastewater system.
- Indicate other significant features or improvements of the subject property, such as streams, ponds, irrigation ditches, wells, floodplains, wastewater systems, corrals, fences, towers, overhead power lines, etc.
- Commercial, Industrial, and Multi-Family parcels must identify landscaping and parking areas.
- Indicate the driveway location(s).

PARCEL BOUNDARY MAP REQUIREMENTS

- Map showing a half-mile radius around the parcel to be rezoned, oriented with the North Arrow.
- The parcel requested to be rezoned shall be highlighted on the map.

APPLICATION SIGNATURE(S) AND ACCESS PERMISSION

Right to ingress property for assessment, evaluation, and inspections.

I, the undersigned, hereby grant authorized Platte County Personnel the right to enter onto this said land/property for all inspection, assessment, and/or evaluation purposes necessary to process this Rezone application. I certify, to the best of my knowledge, that all the information in this application is true and correct, and that I am the owner of the above-described property or have been authorized by the owner to make this application as his/her agent.

_____ _____

Signature of Applicant(s) Date

R-_____-_____

PLANNING OFFICE USE ONLY

Date completed application received: _____ Application Fee Total: _____

Planning & Zoning Commission Public Hearing Date: _____ Approved □ Disapproval □

Board of County Commissioners Public Hearing Date: _____ Approved □ Disapproval □

This Rezone request is granted □ with/□ without conditions; this _____ day of _____, 2021.

_____
County Commissioner Chairman

Rezone Conditions: _____

_____

_____

R-_____-_____

PROJECT – BUILDIND CERTIFICATE

Planning Office – 600 9th Street – Wheatland, Wyoming 82201
Office 307.322-2962 – Fax 307.322.2968

All applications must include the following:

- ☐ **Application:** Fill out the application form completely. *Incomplete applications will be returned.*
- ☐ **Fees:** All applicable fees. Check or Cash only, the planning office cannot process credit cards.
- ☐ **Site Plan:** Complete site plan
- ☐ **Project Plan:** Engineer and/or design drawings and information.
- ☐ **Easements:** Include a copy of any easements granting you legal access to the property.
- ☐ **Encroachment License:** Copy of the encroachment license for any driveway access of a State or County Road. For more information, contact WYDOT or Platte County Road and Bridge.
- ☐ **Proof of Ownership:** Book and page number of the deed, copy of the deed, lease, or contract for purchase.
- ☐ **Landscaping Plan:** Commercial, Industrial, and Multi-Family parcels are required to provide a landscaping plan.
- ☐ **Parking Plan:** Commercial, Industrial, and Multi-Family parcels are required to provide a parking plan.

*Commercial, Industrial, and public buildings may require a permit and inspection from the State Fire Marshall's Office www.wyofire.state.wy.us

IMPORTANT NOTICES

- ❖ One application per project.
- ❖ Application must include an email address, or the application will be considered incomplete. Incomplete applications will be returned.
- ❖ Building Certificates expire two years from the date of approval. Applications must be approved by the Board of County Commissioners **before** any construction begins. This applies to all principal structures and accessory buildings.
- ❖ It is recommended that you obtain your building certificate (building permit) and wastewater (septic) permit at the same time. If you are building on a small lot, this is highly recommended to ensure that the proper location for the septic field can be determined. For wastewater permits and information go to deq.wyoming.gov.
- ❖ The applicant agrees to abide by the Platte County Planning and Zoning Rules and Regulations as well as any requirements specific to the property required by Platte County. Application requirements can vary depending on the zoning of the property. The Platte County Planning and Zoning Rules and Regulations are available on the Platte County website, www.plattecountywyoming.com. Platte County does not review applications in the context of any existing covenants for the subject property. It is the property owner's sole responsibility to ensure that all covenants are met.
- ❖ Call Wyoming One Call at least two business days before you intend to dig or submit a web ticket at onecallofwyoming.com. In-state call 811 Out-of-state call 888-987-3742

STRUCTURE BUILDING CERTIFICATE

Applicant Name: ______________________________ Phone No.: _________________________

Mailing Address: ____

E-mail Address: ____

If the applicant is other than the owner of the property for which this building certificate is being sought, the applicant must provide separate written approval from the owner, or the owner may indicate approval by signing below.

Owner Name: ______________________________ Signature.: ______________________________

Mailing Address: ____

E-mail Address: _________________________________ Phone No.: _________________________

Proof of Ownership: Deed Book ______ Page ______, ☐ Deed, Lease, Purchase Contract Attached

Owner Name: ______________________________ Signature.: ______________________________

Mailing Address: ____

E-mail Address: _________________________________ Phone No.: _________________________

Proof of Ownership: Deed Book ______ Page ______, ☐ Deed, Lease, Purchase Contract Attached

Owner Name: ______________________________ Signature.: ______________________________

Mailing Address: ____

E-mail Address: _________________________________ Phone No.: _________________________

Proof of Ownership: Deed Book ______ Page ______, ☐ Deed, Lease, Purchase Contract Attached

Owner Name: ______________________________ Signature.: ______________________________

Mailing Address: ____

E-mail Address: _________________________________ Phone No.: _________________________

Proof of Ownership: Deed Book ______ Page ______, ☐ Deed, Lease, Purchase Contract Attached

Owner Name: ______________________________ Signature.: ______________________________

Mailing Address: ____

E-mail Address: _________________________________ Phone No.: _________________________

Proof of Ownership: Deed Book ______ Page ______, ☐ Deed, Lease, Purchase Contract Attached

Contractor: _____Phone No.: _____

Mailing Address: _____

E-mail Address: _____

Sub-contractor: _____Phone No.: _____

Mailing Address: _____

E-mail Address: _____

Sub-contractor: _____Phone No.: _____

Mailing Address: _____

E-mail Address: _____

Sub-contractor: _____Phone No.: _____

Mailing Address: _____

E-mail Address: _____

Sub-contractor: _____Phone No.: _____

Mailing Address: _____

E-mail Address: _____

Legal description of property for which this Building Certificate is being requested:

Subdivision: _____ Tract/Lot(s): _____ Quarter Section: _____

Of Section: _____ Township _____ North, Range _____ West

Physical address(es) of property(s) for which this Building Certificate is being requested:

_____

_____

_____

Current Land Use: _____

Zoning Classification: _____

Description of proposed construction, addition, or reconstruction: _____

_____

_____

_____

Number of sq. ft. of new structures, reconstruction, or addition: _____

Total Construction Value: _____ ***Total value of all construction work including finish work, painting, roofing, electrical, plumbing, heating, A/C, elevators, fire protection systems, and any other permanent equipment.* Does not include land, landscape, or hardscape. Fee is Value x 0.005.

PROPOSED USE AND ADDITIONAL INFORMATION

Is the project located within a floodplain? □ Yes □ No *Floodplain maps are available at msc.fema.gov*

Is the project located within the aquifer? □ Yes □ No

Water source: □ Well □ Hauled □ Public Utility □ no H2O
Well permits are processed through the State Engineer's Office 307-777-7254

Wastewater permit has been applied for with the Department of Environmental Quality: □ Yes □ No

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SITE PLAN REQUIREMENTS

- Show the entire lot or parcel with dimensions and orient the drawing with the North Arrow.
- Indicate adjacent roads and their names.
- Indicate locations and outside dimensions of all buildings.
- Setbacks are required for buildings and/or project structures. Indicate setbacks from property lines, easements, rights-of-way, and roads for all proposed structures and provide the distances.
- Setbacks are required for both the well and wastewater (septic) system. Indicate setbacks from property lines with distances to well and wastewater system.
- Indicate other significant features or improvements of the subject property, such as streams, ponds, irrigation ditches, wells, floodplains, wastewater systems, corrals, fences, towers, overhead power lines, etc.
- Commercial, Industrial, and Multi-Family parcels must identify landscaping and parking areas.
- Indicate the driveway location(s).

APPLICATION SIGNATURE(S) AND ACCESS PERMISSION

Right to ingress property for assessment, evaluation, and inspections.

I, the undersigned, hereby grant authorized Platte County Personnel the right to enter onto this said land/property for all inspection, assessment, and/or evaluation purposes necessary to exercise this certificate/permit. I certify, to the best of my knowledge, that all the information in this application is true and correct, and that I am the owner of the above-described property or have been authorized by the owner to make this application as his/her agent.

_____ _____

Signature of Applicant(s) Date

PLANNING OFFICE USE ONLY

Date completed application received: _____ Application Fee Total: _____

Zoning Classification: _____ Special Use Permit number if applicable: _____

Request complies with the current zoning rules and regulations: □ Yes □ No, if no, please explain: _____

_____

Physical Address: □ Existing □ Not requested □ Assigned: _____

FACTSHEET: Slaughterhouse Permitting

INTRODUCTION

This Fact Sheet provides information on the appropriate Department of Environmental Quality (DEQ) permit(s) for those interested in the construction and operation of small wastewater systems, specifically slaughterhouses (aka meat processors or meat packing plants). Underground Injection Control (UIC) Permit coverage for slaughterhouse-derived waste discharge is required under Wyoming Water Quality Rules (WWQR) Chapter 27. Permit coverage is required to protect groundwater and human health. Certain constituents within slaughterhouse-derived waste can negatively impact groundwater quality; groundwater is often used to supply domestic drinking water to public and private users.

WHEN IS A UIC PERMIT VERSUS A CHAPTER 3 PERMIT NEEDED?

All small wastewater systems are regulated under W.S. 35-11-301. UIC facilities, also referred to as Class V facilities, are regulated under WWQR Chapter 27 and are permitted by the Groundwater Section of the Water Quality Division (WQD). Permits to construct, issued by the Water and Wastewater Section of the WQD, are regulated under WWQR Chapters 3 and 25. Permits for small wastewater facilities, as defined by W.S. 35-11-103(c)(ix), are issued by the DEQ Water and Wastewater Section and delegated entities. Facilities will be required to obtain a DEQ-issued UIC permit in accordance with WWQR Chapter 27 when:

- The facility includes non-domestic waste.
- The facility discharges more than 2,000 gallons per day (gpd) or is designed to handle more than 2,000 gpd at peak daily flow.

WHAT TYPE OF PERMIT DO I NEED?

The type of permit needed depends on the type and volume of wastewater that will be discharged.

- Chapter 3 Permit to Construct: Facilities collecting waste directly into a holding tank that **will not discharge** to a septic system and associated leachfield or lagoon may be issued a Chapter 3 Permit.

- Individual UIC Permit: WWQR Chapter 27 defines slaughterhouse process water and waste disposal facilities as a 5C3 Industrial and Commercial state subclass of the UIC Class V designation. A 5C3 category Individual Permit is necessary for the discharge of volumes in excess of 2,000 gpd average. When a 5C3 facility receiving slaughterhouse wastes can demonstrate that no violations of groundwater standards will occur, the facility shall be designed for the following minimum disposal capacities:
  - 300 gpd for plant cleanup, plus
  - 25 gallons per head (gph) of cattle slaughter capacity, or
  - 40 gph of hog slaughter capacity, or
  - 35 gph of sheep slaughter capacity, or
  - Appropriate capacity for any other species slaughtered on a per head basis.

  An Individual Permit is subject to a 30-day public notice requirement. The timeframe to issue a permit from receipt of a permit application is 90 to 120 days but may be longer if an application is determined incomplete.

- General UIC Permit: A 5C6-5E5 General Permit covers Small Commercial Disposal Systems and Small Domestic Subsurface Fluid Distribution Systems in accordance with WWQR Chapter 27. These small commercial disposal systems inject wastewater that is of similar quality to domestic sewage, but does not technically meet the definition of domestic sewage in quantities of less than 2,000 gpd. Slaughterhouses are one example of 5C6

facilities that may be appropriate for coverage under the General Permit. General Permits are issued within 60-days of application receipt and not subject to public notice requirements.

- Although an application for a General Permit may be made for the above-referenced facilities, discharges that may pose a threat to a drinking water aquifer or may present potential health or environmental impacts may require an application for an Individual Permit.

If you have any questions about the type of permit you need, please contact DEQ prior to completing an application. Permit applications are available on DEQ's websites:

- Chapter 3 Permits - http://deq.wyoming.gov/wqd/permitting-2/resources/obtaining-permit/
- Individual Permit (UIC Form 2a) and the General Permit (UIC Form 2b) - http://deq.wyoming.gov/wqd/underground-injection-control/resources/forms/

WHAT ARE THE CONSTRUCTION REQUIREMENTS?

- WWQR Chapter 3 Water and Wastewater permit – non-discharging holding tanks should be used to collect the blood from the kill room for disposal with a rendering plant, disposed at the local permitted transfer station or permitted landfill or composted on-site in accordance with DEQ Solid Waste Guidance documents.
- Individual 5C3 Permit – disposal capacities as above and
  1. Designed to prevent the disposal of blood and viscera into the septic system except as a small incidental portion of the total flow. Blood and viscera shall be sent to a rendering plant or other approved disposal or recycling system.
  2. Includes a grease trap ahead of the septic system with a total capacity equal to one-half of the total required capacity of the septic tank.
  3. Includes an effluent filter on the discharge of the second tank to prevent hair, light fats, and viscera from building up in leachfields.
  4. Meets the construction standards and separation distances appropriate for the design flow as shown in WWQR Chapter 25.
- General Permit 5C6 and 5E5 systems will be allowed to continue using the Water and Wastewater small system design package instead of separate (Professional Engineer) designed systems.
  1. Small producers (2-3 slaughters per day) should comply with items 1, 2, and 3 above so that the grease trap and septic tanks are in series with a second tank and include an aerated holding tank prior to the leachfield or lagoon.
  2. Large producers (more than 3 slaughters per day) should use a facultative lagoons system that can be aerated.
  3. All systems shall meet the construction standards and separation distances appropriate for the design flow as shown in WWQR Chapter 25.

WHAT OTHER DEQ PERMITS ARE REQUIRED?

- Dead animal management is regulated under the Solid Waste Rules and disposal of carcasses should occur at a permitted landfill. Contact your local landfill to determine any local waste acceptance criteria. In addition, Solid Waste Guideline #27 summarizes options available in Wyoming for dead animal management. Further, Solid Waste Guideline #17 provides recommendations for composting dead animals. Solid Waste Guidance documents can be found on DEQ's website: http://deq.wyoming.gov/shwd/solid-waste/resources/guidance-standards/. Please contact Suzanne Engels at (307) 777-5447 or suzanne.engels@wyo.gov for more information.
- Coverage under a WYPDES industrial storm water permit is required. Please contact Barb Sahl at (307) 777-7570 or barb.sahl@wyo.gov for more information on storm water permitting.

- If planning to surface discharge wastewaters generated from slaughterhouse and/or meatpacking operations, a WYPDES permit may be required. Please contact Kathy Shreve at (307) 777-7093 or kathy.shreve@wyo.gov for more information.
- Potential for air emissions such as use of a boiler or emergency generator(s) may require an Air Quality Permit. Please contact Andrew Keyfauver at (307) 777-7045 or andrew.keyfauver@wyo.gov for more information.
- Current Wyoming Water Quality Rules are available at https://rules.wyo.gov. Please contact DEQ staff if you need assistance.

FOR MORE INFORMATION ABOUT SLAUGHTERHOUSE PERMITTING, PLEASE CONTACT THE FOLLOWING DEQ WATER QUALITY DIVISION STAFF:

Permitting: Lily Barkau at (307) 777-7072 or lily.barkau@wyo.gov

Engineering: Dennis Lewis at (307) 777-7088 or dennis.lewis@wyo.gov

UNDERGROUND INJECTION CONTROL
CLASS V
APPLICATION FOR INDIVIDUAL PERMIT COVERAGE
(Wastewater Facilities)

APPLICATION INSTRUCTIONS

The following instructions outline the procedures to follow and information needed for a non-domestic wastewater Individual Class V application as required by WWQRR Chapter 27. For Domestic Wastewater Disposal Facilities (i.e. domestic-waste septic systems) use UIC Application Form UIC-1-Vb. The WDEQ has sixty (60) days to determine application completeness. Individual permit applicants have a mandatory thirty (30) day public notice period.

For guidance or to resolve permit application submittal issues, please call (307)777-7072.

A. The applicant shall submit the application in duplicate (one (1) original and one (1) electronic copy) to the following address:

Wyoming Department of Environmental Quality
Water Quality Division
ATTN: UIC Program
200 W 17th St - 2nd Floor
Cheyenne, WY 82002

B. Applications shall be signed as follows:
   1) An application submitted by a corporation must be signed by a president, secretary, vice president or treasurer of the corporation in charge of a principal business function, or other person who performs a similar decision making function for the corporation.
   2) An application submitted by a partnership or sole proprietorship shall be signed by a general partner or the proprietor, respectively.
   3) An application submitted by a municipality, or a state, federal, or other public agency shall be signed by either the principal executive officer or ranking elected official. "For" or "by" signatures are not allowed. Electronic signatures are not allowed.

C. Applications are reviewed for completeness and technical adequacy. During the completeness review, the applicant may be contacted for clarification or additional information. An application will not be processed until all required information has been submitted. Severely lacking applications, applications submitted solely as electronic forms, applications without original signatures, applications with illegible information, or applications with information not submitted in a timely manner shall be returned to the applicant. If your application is determined to be complete and technically adequate, a draft permit and Fact Sheet shall be prepared by the UIC Program and transmitted to you for review. In addition, notification shall be provided to other interested entities. A mandatory thirty (30)-day public comment period is required and if no comments or requests for a public hearing are made during the public comment period, the Administrator shall make a final determination for permit issuance or denial within 30 days after the public comment period.

D. Applicants shall complete the entire application form. If you feel that any portion of the application does not apply to your facility, respond "not applicable" and provide your rationale as to why you believe the requirement does not apply to your facility. Applicants are not required to submit the instruction/example pages (annotated in the footer) with their applications.

E. Use TABLE 1 (below) to determine your facility type (see Section 5 of permit application). Please note that 5C4 and 5E2 facilities are prohibited (banned), if you have one of these facilities please contact our office to resolve it.

TABLE 1: UIC Facility Types (Check only one box corresponding to your facility)

INDIVIDUAL PERMITS (WWQRR Chapter 27, Section 9)			
Type		**Description**	**Details**
☐	5A3	Cooling Water Return Flow Facility	Receive non-contact cooling water from industrial processes, both open and closed-loop systems.
☐	5B3	Saline Water Intrusion Barrier Facility	Receive fresh water to prevent the continued migration of saline water into a fresh water aquifer. Includes projects installed to control contaminant plumes by injection of clean water.
☐	5B5	Non-Department Controlled Remediation Facility	Injection of fluids used to prevent, control, or remediate aquifer pollution, which are not owned or controlled by the DEQ.
☐	5C1	Air Scrubber Waste Disposal Facility	Injects waste from air scrubbers used to remove sulfur, fly ash, or other contaminants.
☐	5C2	Water Treatment Brine Disposal Facility	Receive brine from water softening or other water treatment.
☐	5C3	Industrial Process Water and Waste Disposal Facility	Receive wastes generated by industrial or commercial processes. Examples include, but are not limited to wastes generated by car washes, taxidermy, metal plating, printing, silk screening, refining, slaughter houses, and chemical manufacturing facilities.
☐	5C5	Coal Bed Methane Injection Facility	Inject groundwater produced in the process of coal bed methane extraction into a receiving aquifer containing water of the same or lower class of use.
☐	5D3	Improved Sinkholes	Receive stormwater runoff from developments located in karst topographic areas.
☐	5D4	Industrial Drainage Facilities	Receive stormwater runoff from areas susceptible to spills, leaks, and other chemical discharges.
☐	5E1	Aquaculture Return Flow Facilities	Receive injectate from aquaculture operations.
☐	5E3	Large-Scale Domestic Septic Systems	Receive more than 2,000 gallons per day of domestic sewage with only primary treatment of effluent (i.e. septic tank) OR any facility injecting a combined total of 2,0000 gallons or more of domestic sewage from multiple systems under the same owner within any 5 acres.
☐	5E4	Domestic Wastewater Treatment Plant Disposal Facilities	Disposal of treated domestic waste after treatment to at least secondary treatment standards (NOT domestic septic tank-leachfield systems)
☐	5F2	All Other Facilities	All other facilities that inject fluids into or above an underground source of drinking water, and do not fall into Classes, I, II, III or IV injection facilities.

BANNED (PROHIBITED) FACILITY TYPES (WWQRR Chapter 27, Section 20) – Contact WDEQ to resolve		
Type	**Description**	**Details**
5C4	Automotive Waste Disposal Facilities	Inject waste from floor drains or sinks where repair work is done on machinery of any description
5E2	Untreated Domestic Sewage Disposal Facilities	Receive untreated domestic sewage from single or multiple sources. Does not include subsurface fluid distribution systems with septic tanks ahead of the subsurface fluid distribution system. Includes all cesspools, regardless of capacity.

F. AREA OF REVIEW CALCULATIONS

The Area of Review is the area for which information and analyses shall be submitted as part of an Underground Injection Control (UIC) permit application. The Area of Review (AOR) must include all portions of an aquifer that will be affected in a measureable way within ten (10) years of permit issuance.

(1) For individual permits, the applicant may use an area of review that includes the quarter/quarter section (40 acre tract) where the facility is located and all of the adjacent quarter/quarter sections, provided the radius of volumetric fillup (calculations provided below) is less than the default radius (a circle of approximately 2,230-ft in radius). This will yield a total AOR of nine (9) quarter/quarters or a total of 360 acres with the injection facility near its center.

(2) A radius of volumetric fillup may be used to establish the AOR. The simplest formula allowable assumes that the injectate completely displaces all formation water in a circle around the point of injection. Other formulas may be used, if so, provide documentation as to applicability, source, and data used in the calculation. The simplest formula is:

$$R = \sqrt{\frac{Qt}{\pi Hp}} =$$

Where:

R = Radius of Volumetric Fillup (feet)

H = Thickness of the Injection Zone (feet)

t = Time of injection (days, proposed life of well)

Q = Injection Rate (cubic feet per day)

p = Porosity, expressed as a pure decimal

π = 3.14

Note: Conversion Factor for gallons to cubic feet = 0.13368, for barrels to cubic feet = 5.61458

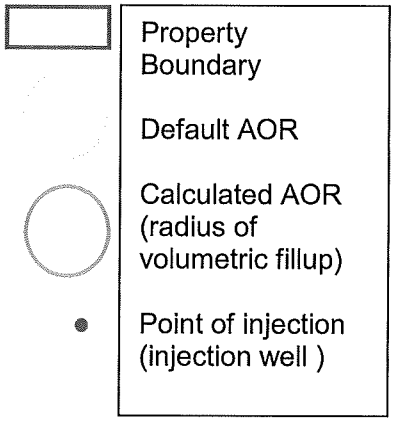
(3) Other methodologies/formulas may be used. If electing to use an alternative formula/methodology, the formula/methodology must be provided and described. All inputs must be provided along with a description of how the inputs were calculated and/or determined, including any citations. Also provide a rationale as to why the alternative formula/methodology was selected, and its applicability in this instance.

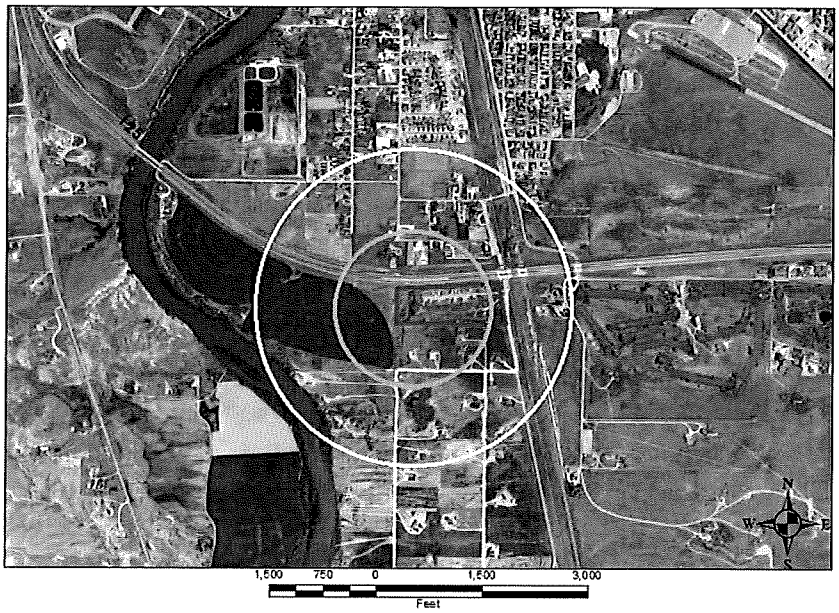
NOTE: For a facility injecting a maximum of less than 10,000 gallons per day, the AOR is determined using method (1) above.

For a facility injecting a maximum of 10,000 gallons per day or more, the AOR is the larger of the values determined using all the above methods. (See following examples A and B).

EXAMPLES: AREA OF REVIEW CALCULATIONS

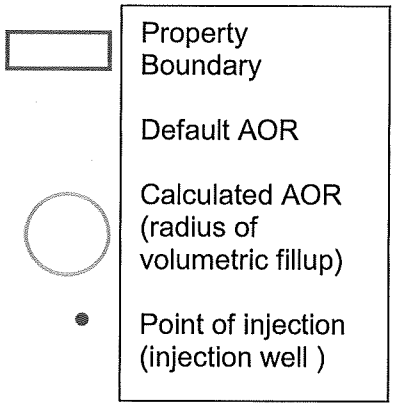
AOR Visual Representation – Example A

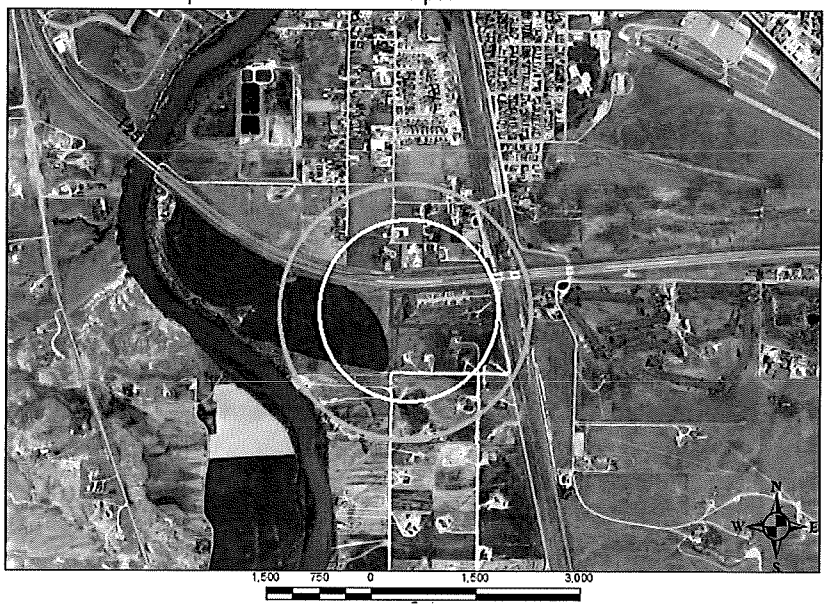




In Example A, the yellow circle depicts the default AOR radius. The radius of volumetric fillup was calculated and is represented by the blue circle. In this case, the default AOR is larger, therefore the AOR for this injection well is the default (yellow circle) AOR.

AOR Visual Representation – Example B





In Example B, the yellow circle depicts the default AOR radius. The radius of volumetric fillup was calculated and is represented by the blue circle. In this case, the radius of volumetric fillup is larger, therefore the AOR for this injection well is the calculated radius of volumetric fillup (blue circle) AOR.

G. EXAMPLE: Completed Area of Review Legal Description (See Section 5, Item 4 of permit application)

In this example, the facility has one injection well (DW #1) located in the NENE, Section 15, Township 44N, Range 102W. The permittee has elected to use the default method of calculating their AOR, as their maximum proposed wastewater flows are below 10,000 gallons per day. The AOR should then be described as follows:

Well ID	Township	Range	Section	Quarter	Quarter/Quarter
DW #1	44N	102W	15	NE	NE*
				NE	NW
				NE	SW
				NE	SE
			14	NW	SW
				NW	SW
			11	SW	SW
			10	SE	SE
				SE	SW

*Denotes injection well location

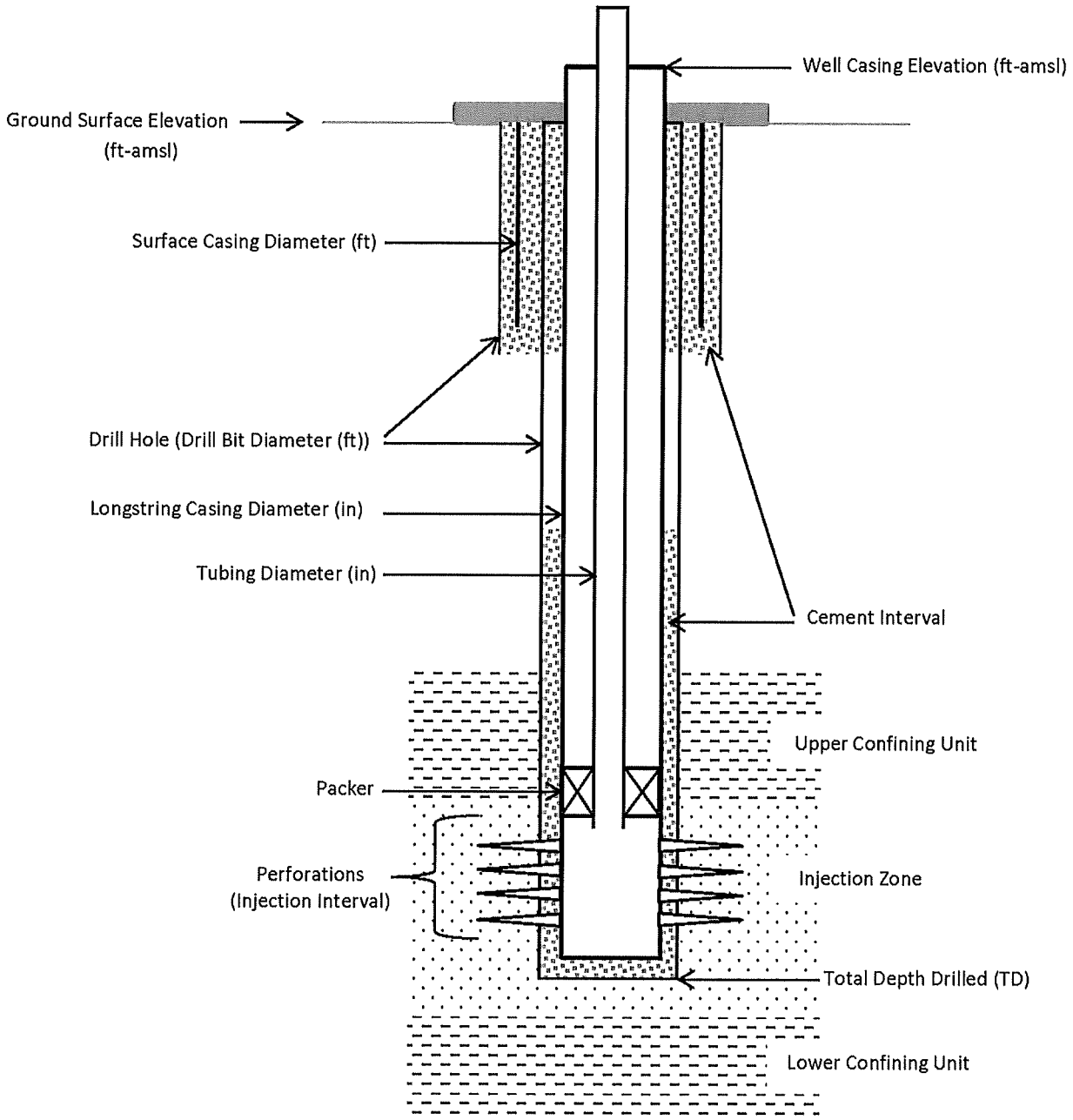
Complete one row for each quarter/quarter. Complete additional tables for each injection well being permitted or renewed.

If the facility's injection well(s) are located in more than one quarter/quarter, the AOR shall be expanded to include all the quarter/quarters that the injection well(s) are located within and all adjacent quarter/quarters. For example, using the above example, if the facility has, in addition to the injection well described above (DW #1), an additional injection well located in the NENW, Section 15, Township 44N, Range 102W, (DW #2) the AOR should then be described as follows:

Well ID	Township	Range	Section	Quarter	Quarter/Quarter
DW #1	44N	102W	15	NE	NE*
				NE	NW
				NE	SW
				NE	SE
			14	NW	SW
				NW	SW
			11	SW	SW
			10	SE	SE
				SE	SW
DW #2	44N	102W	15	NE	NW*
				NE	SW
				NE	SE
				NE	NE
				NW	NE
				NW	SE
			10	SE	SE
				SE	SW
				SW	SE

*Denotes injection well location.

H. EXAMPLE VERTICAL INJECTION WELL DIAGRAM



UNDERGROUND INJECTION CONTROL PROGRAM
CLASS V
APPLICATION FOR INDIVIDUAL PERMIT COVERAGE
(Non-domestic Wastewater Facilities)

AGENCY USE ONLY		
Date Application Received	Permit Number	Facility Number

Use this application for non-domestic wastewater Class V injection wells (see attached Table 1 for a list of facility types that require permit coverage). Please answer every item on this form to the best of your knowledge and attach the required documents. The WDEQ has sixty (60) days to determine application completeness.

SECTION 1: TYPE OF APPLICATION (Check one)

☐ NEW FACILITY PERMIT ☐ PERMIT RENEWAL_____
(Provide UIC permit and/or facility #)

☐ PERMIT MODIFICATION_____
(Provide UIC permit and/or facility #)

SECTION 2:

COMPANY/OWNER CONTACT INFORMATION

COMPANY NAME:_____

COMPANY MAILING ADDRESS:_____

COMPANY CONTACT:_____ PHONE NUMBER:_____

TITLE:_____ EMAIL ADDRESS:_____

CONTACT TYPE (Choose one or more) ☐ OPERATOR ☐ CONSULTANT ☐ OWNER (Please specify business type)

☐ OTHER (Please specify)_ _____

PRIMARY CONTACT ☐ YES ☐ NO CONTACT ROLE:_____

SECTION 3: FACILITY CONTACT INFORMATION

FACILITY NAME:_____ COUNTY:_____

FACILITY MAILING
ADDRESS:_____

FACILITY PHYSICAL
ADDRESS:_____

FACILITY CONTACT:_____ PHONE NUMBER:_____

TITLE:_____ EMAIL ADDRESS:_____

CONTACT MAILING
ADDRESS:_____

CONTACT TYPE (choose one or more)

☐ OPERATOR ☐ CONSULTANT ☐ OWNER (Please specify type)_____

☐ OTHER (Please specify)_____

PRIMARY CONTACT: ☐ YES ☐ NO CONTACT ROLE:_____

List all persons or firms authorized to act on behalf of the applicant during the processing of the application. Provide contact names, mailing addresses, phone numbers, and e-mail addresses for all additional contacts.

SECTION 4: FACILITY LOCATION INFORMATION

FACILITY LOCATION

Township_____Range_____Section:_____Quarter/Quarter_____

Latitude: NAD83, decimal degrees:_____

Longitude:NAD83, decimal degrees:_____

LAND OWNERSHIP_____ If Other, describe:_____

SECTION 5: WELL/FACILITY CLASSIFICATION AND PERMIT TYPE

A. Determine your Class V facility classification (select one, see Table 1, Item E in "Instructions"):

Well/Facility Classification _____

B. Select your permit type: ☐ Area Permit ☐ Single Permit

If the facility only has one injection well, select "Single Permit", if it has multiple injection wells, select "Area Permit", provided that:

1. The receiving formation is the same for all injection wells.
2. The wells are owned by the same person or company.
3. The injectate for all wells is similar in terms of chemistry and composition (similar waste streams).

If applying for an Area permit, provide information (as an attachment to this application) to satisfy all items in this application for each injection well.

C. Attach a list of all other permits your facility has been required to obtain prior to construct and/or commencement of operations. Include permit number or permit designation and regulating authority.

SECTION 6: WELL/FACILITY PERMIT INFORMATION

A. If the facility owner/operator is not the owner of the surface rights where the facility is located, attach copies of the access agreement between the owner(s) and the facility owner/operator. This requirement can be met by having the owner(s) of the property write a letter consenting to the activities proposed in this application. If there are more than one surface rights owners, attach a table detailing surface rights owner's names, mailing addresses, and telephone numbers.

B. Provide a brief description of the nature of the business and the activities at the facility being permitted:

C. Provide the types, sources, and general descriptions of the fluids proposed for injection, including chemical, physical, radiological, and toxic characteristics (attach analytical data to this application, if available, and/or MSDS sheets).

D. Facility's average disposal capacity in gallons or barrels per day (circle one):_____

E. Facility's maximum disposal capacity in gallons or barrels per day (circle one): _____

F. Depth of injection zone (feet below ground surface)_____

G. Required permit application attachments:

1) Plan view of the facility and property showing the location of the injection well(s).

2) A topographic map and other pertinent maps, extending at least one (1) mile but not less than the Area of Review for Individual Permit applications.

The topographic map shall depict all of the following:

a) Property boundaries and surrounding land uses,
b) The facility and each of its intake and discharge structures,
c) Each well, drywell, or subsurface fluid distribution systems where fluids from the facility are injected underground,
d) Other wells, springs, surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant.
e) North arrow
f) Map scale
g) Topographic interval (feet)

3) Construction and engineering details in accordance with WWQRR Chapter 25 (septic systems), Chapter 26 (wells) and/or Chapter 27 (Class V systems):

a) Vertical well construction information:

i.) For new wells, provide proposed total depth, proposed bit sizes, casing string details, tubing diameter, cementing plans, and wellhead type/description.
ii.) For existing wells, provide all the information in (i) above, and a copy of the daily drilling logs for the well.
iii.) Provide a detailed diagram that shows the following
1. Hole size(s)
2. Casing string details
3. Cemented portions of the well outside of each casing string (if any), include cement bond logs.
4. Receiving formation
5. Packer depth
6. All underground sources of drinking water.
iv.) Include complete wellbore lithology and copies of any geophysical logs.
v.) Well information, including:
1. Average injection rate (in barrels or gallons per day, please indicate units)
2. Maximum injection rate (in barrels or gallons per day, please indicate units)
3. Injection interval name, description, and thickness
4. Surface well casing elevation
vi.) For Septic Systems only, provide the following:
1. Drainfield Construction Information
a. Drainfield top and bottom elevations
b. Size and location of drainfield,
c. Size, construction, and location of all holding tanks (septic tanks),
d. Piping details
e. Depth to static water level

Details should be sufficient to show compliance with all applicable sections found in Chapters 26 and 27, Wyoming Water Quality Rules and Regulations.

4) For vertical injection well(s), complete Table 2, Section 5 and an injection well diagram (see example provided in Instructions, Section H) for each proposed, renewing, or modified injection well. Attach additional tables as needed.

TABLE 2: VERTICAL WELL DETAILS

Well ID				
SEO or WOGCC Permit #				
Latitude (NAD83, decimal degrees)				
Longitude (NAD83, decimal degrees)				
Well Location (T/R/S/Qtr/Qtr)				
Total Depth Drilled				
Packer Depth (if applicable)				
Well Casing Elevation				
Casing Diameter				
Drill Bit Diameter				
Tubing Diameter				
Receiving Formation(s) (Injection Zone(s))				
Injection Interval Top Depth				
Injection Interval Bottom Depth				
Upper Confining (UC) Formation				
UC Formation Top Elevation				

NOTE: All new facilities must complete and submit an Injection Well Notification of Construction Completion, Form UIC-4, to the UIC Program upon construction completion for each new injection well.

H. Attach additional information as required by permit type:
   1) Facility type 5B5, see Chapter 27, Section 13(e)
      a) A plan to ensure contaminants don't enter the waste stream.
      b) Information showing that the injection will accomplish the goals stated in the permit application.
      c) Target restoration values for the groundwater in the affected areas.

I. Applicant must submit information necessary for the department to make an assessment of the vulnerability of the environmental and public health from the injection into the Class V well, as follows:

1) Depth to seasonally high groundwater in the shallowest aquifer:_____

2) For all wells identified within the area of review, provide a table containing the following:
   a) Well ID,
   b) Wyoming State Engineer's Office well permit number,
   c) Well owner's name,
   d) Well depth,
   e) Well screening intervals,
   f) Well use,
   g) Well locations in relation to the facility.

3) Provide documentation that the disposal capacity of the facility in gallons per day was calculated according to Table 1, Chapter 25, Section 2.

   Does the facility have a meter to measure injectate volume? ☐ Yes ☐ No
   If yes, attach the previous two (2) years injectate volume records, if applying for a permit renewal or modification.

4) Provide information on groundwater quality, lithology, geology, and hydrology in the formations underlying the facility.

J. Additional information as required by permit type:

1) Facility type 5B5, see Chapter 27, Section 13(e)
   a) A plan to ensure contaminants don't enter the waste stream.
   b) Information showing that the injection will accomplish the goals stated in the permit application.
   c) The target restoration values for the groundwater in the affected areas.
   d) If proposing to utilize a remediation method that has the potential to cause an exceedance of the Class of Use for the receiving formation/aquifer for any constituent listed in WWQRR, Chapter 8, Table 1, the permittee must also submit the following:
      i. Background (ambient) groundwater quality data for any constituents of concern identified by the UIC Program,
      ii. A proposal for monitoring the effect of the remediation on groundwater quality in the receiving formation/aquifer, to include, but not limited to:
         1. Downgradient groundwater monitoring well(s), including siting and construction details,
         2. A proposed monitoring schedule,
         3. A proposed sampling and analysis plan,
         4. A plan for altering/halting the remediation activities in the event the remediation causes a demonstrable negative change in formation/aquifer water quality.

2) Facility type 5C5 (Coal Bed Methane Produced Water Injection):
   a) Attach a description of provisions proposed to control waste stream quality and prevent the injection of hazardous wastes. Injection of drilling fluids, spent oilfield chemicals, industrial wastes, and/or hazardous wastes is not allowed.
   b) Attach information used to determine the receiving formation's fracture pressure as defined in WWQRR, Chapter 27, and provisions that shall be implemented to control injection pressures.
   c) Attach sufficient groundwater quality data (see WWQRR, Chapter 8, Table 1) to classify each receiving aquifer. If analyses are not available during the application process, attach a plan describing how groundwater quality data will be obtained during the well completion process.
   d) Attach a copy of the proposed Mechanical Integrity Testing methods, as required by WWQRR

Chapter 27, Section 13 (p)(vii).

e) Attach proof that all surface rights, mineral, water rights, and oil and gas and/or coal rights owners located within a ½ mile of the facility have been notified of your intent to obtain coverage under a General Permit.

f) Attach copies of the well construction plans and all surface facilities used as part of the coal bed methane injection facility.

g) Attach a description of the proposed pre-treatment plan to ensure that biological, hazardous, toxic or potentially toxic materials are not discharged to groundwater at concentrations greater than the class of use standards established in WWQRR, Chapter 8.

h) Attach a Spill Prevention Plan describing how biological, hazardous, toxic or potentially toxic materials will be prevented from entering the facility's waste stream prior to injection.

i) Attach a description of the disinfection process that will be implemented if analyses demonstrate that coliform, sulfate reducing, or iron fixing bacteria are present in groundwater pumped from the coal seam(s).

j) As of July 1, 2018, submission of financial assurance as established in WWQRR, Chapter 27, Section 19(C).

NOTE: All 5C5 applicants are also required to have a WYPDES permit (http://deq.wyoming.gov/wqd/wypdes/)

3) A calculation of the Area of Review (AOR) (see Instructions, Item F) for each injection well.

a) Attach documentation explaining the source and use of the data and calculation method(s) used to determine the AOR for the proposed/renewed/modified facility.

b) Attach a legal description of each injection well's AOR in Township, Range, Section, and Quarter/Quarter (general land survey system) coordinates to the nearest ten (10) acres in Table 3 below. An example of a completed Table 3 is located in the Instructions, Item H.).

Table 3 – Area of Review Legal Description (attach one completed table for each injection well)

Well ID	Township	Range	Section	Quarter	Quarter/Quarter

SECTION 6: CERTIFICATION REQUIREMENTS

A. Sage Grouse Core Determination Area:
Pursuant to the requirements of the Governor's Executive Order 2015-4 (SGEO), Greater Sage Grouse Area Protection, applicants for new UIC permits must determine if any part of their project falls within a Greater Sage Grouse Core Area (SGCA) *before* applying for permit coverage. If any part of the project falls within an SGCA, *the first point of contact for addressing sage grouse issues is the Wyoming Game and Fish Department (WGFD).* Please coordinate with the WGFD and obtain written confirmation of consistency with the Executive Order *prior* to applying for coverage under a UIC permit and submit this documentation as part of the permit application package. Note that the application will not be processed until a letter confirming consistency with the Executive Order has been obtained.

Additional information on SGCAs can be found on the Wyoming Game and Fish Habitat website, at: https://wgfd.wyo.gov/Habitat/Sage-Grouse-Management

Please check one of the following:

☐ Some part, or all, of my project falls within an SGCA and I have contacted the WGFD for an SGEO review. A letter from the WGFD confirming consistency with the Executive Order is attached.

☐ Some part, or all, of my project falls within an SGCA and I have contacted the WGFD for an SGEO review. It does not comply with the SGEO. I have valid and existing rights related to this permit. I have committed to the attached recommendations that will minimize impacts to sage grouse.

☐ By checking this box, I certify that I have reviewed the SGCAs available on-line, and determined that no portion of my project falls within an SGCA. *(No additional requirements apply.)*

B. Access for Inspections:

As part of their [application/renewal/permit modification], the applicant shall certify under penalty of perjury that the applicant has secured and shall maintain permission for Department of Environmental Quality personnel and their invitees to access the permitted [site/facility], including (i) permission to access the land where the [site/facility] is located, (ii) permission to collect resource data as defined by Wyoming Statute § 6-3-414, and (iii) permission to enter and cross all properties necessary to access the [site/facility] if the [site/facility] cannot be directly accessed from a public road. A map of the access route(s) to the [site/facility] shall accompany the [application/renewal/transfer].

I, _____, certify under penalty of perjury that [owner/applicant] has secured and shall maintain permission for the Department of Environmental Quality personnel and their invitees to access the permitted [site/facility], including (i) permission to access the land where the [site/facility] is located, (ii) permission to collect resource data as defined by Wyoming Statute § 6-3-414, and (iii) permission to enter and cross all properties necessary to access the [site/facility] if the [site/facility] cannot be directly accessed from a public road.

C. CERTIFICATION OF THE OWNER/OPERATOR OF THE FACILITY:

Please note: Professional Engineer's and/or Geologist's Certifications are required for new and modified facilities.

" I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all attachments and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment."

Printed Name of Applicant _____ Title _____

Signature of Applicant _____ Date Signed _____

CERTIFICATION OF ENGINEER:

"The engineering designs, plans, and specifications which are included in this application were all done by me or by someone working directly for me. I have reviewed the designs, plans, and specifications and certify that they are all done according to the highest standards of Professional Engineering."

Printed Name of Professional Engineer _____ P. E. Number _____

(SEAL)

Signature of Professional Engineer _____ Date Signed _____

CERTIFICATION OF GEOLOGIST:

"The geologic interpretations, cross sections, and hydrologic studies which are included in this application were all done by me or by someone working directly for me. I have reviewed that work and certify that they are all done according to the highest standards of Professional Geology."

Printed Name of Professional Geologist _____ P. G. Number _____

(SEAL)

Signature of Professional Geologist _____ Date Signed _____

United States
Environmental Protection
Agency

Wastewater Technology Fact Sheet

Anaerobic Lagoons

DESCRIPTION

An anaerobic lagoon is a deep impoundment, essentially free of dissolved oxygen, that promotes anaerobic conditions. The process typically takes place in deep earthen basins, and such ponds are used as anaerobic pretreatment systems.

Anaerobic lagoons are not aerated, heated, or mixed. The typical depth of an aerated lagoon is greater than eight feet, with greater depths preferred. Such depths minimize the effects of oxygen diffusion from the surface, allowing anaerobic conditions to prevail. In this respect, anaerobic lagoons are different from shallower aerobic or facultative lagoons, making the process analogous to that experienced with a single-stage unheated anaerobic digester, except that anaerobic lagoons are in an an open earthen basin. Moreover, conventional digesters are typically used for sludge stabilization in a treatment process, whereas lagoons typically are used to pretreat raw wastewater. Pretreatment includes separation of settlable solids, digestion of solids, and treatment of the liquid portion.

Anaerobic lagoons are typically used for two major purposes:

1) Pretreatment of high strength industrial wastewaters.

2) Pretreatment of municipal wastewater to allow preliminary sedimentation of suspended solids as a pretreatment process.

Anaerobic lagoons have been especially effective for pretreatment of high strength organic wastewaters. Applications include industrial wastewaters and rural communities that have a significant organic load from industrial sources. Biochemical oxygen demand (BOD) removals up to 60 percent are possible. The effluent cannot be discharged due to the high level of anaerobic byproducts remaining. Anaerobic lagoons are not applicable to many situations because of large land requirements, sensitivity to environmental conditions, and objectionable odors. Furthermore, the anaerobic process may require long retention times, especially in cold climates, as anaerobic bacteria are uneffective below 15° C. As a result, anaerobic lagoons are not widely used for municipal wastewater treatment in northern parts of the United States.

Process

An anaerobic lagoon is a deep earthen basin with sufficient volume to permit sedimentation of settlable solids, to digest retained sludge, and to anaerobically reduce some of the soluble organic substrate. Raw wastewater enters near the bottom of the pond and mixes with the active microbial mass in the sludge blanket. Anaerobic conditions prevail except for a shallow surface layer in which excess undigested grease and scum are concentrated. Sometimes aeration is provided at the surface to control odors. An impervious crust that retains heat and odors will develop if surface aeration is not provided. The discharge is located near the side opposite of the influent. The effluent is not suitable for discharge to receiving waters. Anaerobic lagoons are followed by aerobic or facultative lagoons to provide required treatment.

The anaerobic lagoon is usually preceded by a bar screen and can have a Parshall flume with a flow recorder to determine the inflow to the lagoon. A cover can be provided to trap and collect the methane gas produced in the process for use elsewhere, but this is not a common practice.

Microbiology

Anaerobic microorganisms in the absence of dissolved oxygen convert organic materials into stable products such as carbon dioxide and methane. The degradation

process involves two separate but interrelated phases: acid formation and methane production.

During the acid phase, bacteria convert complex organic compounds (carbohydrates, fats, and proteins) to simple organic compounds, mainly short-chain volatile organic acids (acetic, propionic, and lactic acids). The anaerobic bacteria involved in this phase are called "acid formers," and are classified as nonmethanogenic microorganisms. During this phase, little chemical oxygen demand (COD) or biological oxygen demand (BOD) reduction occurs, because the short-chain fatty acids, alcohols, etc., can be used by many microorganisms, and thereby exert an oxygen demand.

The methane-production phase involves an intermediate step. First, bacteria convert the short-chain organic acids to acetate, hydrogen gas, and carbon dioxide. This intermediate process is referred to as acetogenesis. Subsequently, several species of strictly anaerobic bacteria (methanogenic microorganisms) called "methane formers" convert the acetate, hydrogen, and carbon dioxide into methane gas (CH_4) through one of two major pathways. This process is referred to as methanogenesis. During this phase, waste stabilization occurs, represented by the formation of methane gas. The two major pathways of methane formation are:

1) The breakdown of acetic acid to form methane and carbon dioxide:

$$CH_3COOH \quad CH_4 + CO_2$$

2) The reduction of carbon dioxide by hydrogen gas to form methane:

$$CO_2 + 4H_2 \quad CH_4 + 2\ H_20$$

Equilibrium

When the system is working properly, the two phases of degradation occur simultaneously in dynamic equilibrium. That is, the volatile organic acids are converted to methane at the same rate that they are formed from the more complex organic molecules. The growth rate and metabolism of the methanogenic bacteria can be adversely affected by small fluctuations in pH substrate concentrations, and temperature, but the performance of acid-forming bacteria is more tolerant over a wide range of conditions. When the process is stressed by shock loads or temperature fluctuations, methane bacteria activity occurs more slowly than the acid formers and an imbalance occurs. Intermediate volatile organic acids accumulate and the pH drops. As a result, the methanogens are further inhibited and the process eventually fails without corrective action. For this reason, the methane-formation phase is the rate-limiting step and must not be inhibited. For the design of an anaerobic lagoon to work, it must be based on the limiting characteristics of these microorganisms.

Establishing and maintaining equilibrium

The system must operate at conditions favorable for the performance of methanogenic bacteria. Ideally, temperatures should be maintained within the range of 25 to 40 C. Anaerobic activity decreases rapidly at temperatures below 15 C , when water temperature drops below freezing, and biological activity virtually ceases. The pH value should range from 6.6 to 7.6, but should not drop below 6.2 because methane bacteria cannot function below this level. Sudden fluctuations of pH will inhibit lagoon performance. Alkalinity should range from 1,000 to 5,000 mg/L.

Volatile acid concentration is an indicator of process performance because the acids are converted to methane at the same rate that they are formed if equilibrium is maintained. Volatile acid concentrations will be low if the lagoon system is working properly. As a general rule, volatile acid concentrations should be less than 250 mg/L. Inhibition occurs at volatile acid concentrations in excess of 2,000 mg/L. Table 1 presents optimum and extreme operating ranges for methane formation. The rate of methane formation drops dramatically outside these extreme ranges. In addition to adhering to the above guidelines, sufficient nutrients such as nitrogen and phosphorus must be available. Concentrations of inhibitory substances, including ammonia and hydrogen when a high concentration of sulfate ions are present, and

TABLE 1 IDEAL OPERATING RANGES FOR METHANE FERMENTATION

Parameter	Optimum	Extreme
Temp. (C)	30-35	25-40
pH	6.6-7.6	6.2-8.0
Alkalinity (mg/L as $CaCO_3$)	2,000-3,000	1,000-5,000
Volatile acids (mg/L as acetic acid)	50-500	2,000

Source: Andrews and Graef, 1970.

concentrations such as calcium, should be kept to a minimum. Excessive concentrations of these inhibitors produce toxic effects. Depending on its form, ammonia can be toxic to the bacteria as well as affect its concentration. Concentration of free ammonia in excess of 1,540 mg/L will result in severe toxicity, but concentrations of ammonium ion must be greater than 3,000 mg/L to produce the same effect. Maintaining a pH of 7.2 or below will ensure that most ammonia will be in the form of ammonium ion, so higher concentrations can be tolerated with little effect. Table 2 provides guidelines for acceptable ranges of other inhibitory substances.

TABLE 2 CONCENTRATIONS OF INHIBITORY SUBSTANCES

Substance	Moderately Inhibitory (mg/L)	Strongly Inhibitory mg/L)
Sodium	3,500-5,500	8,000
Potassium	2,500-4,500	12,000
Calcium	2,500-4,500	8,000
Magnesium	1,000-1,500	3,000
Sulfides	100-200	>200

Source: WEF and ASCE (1992), reprinted from Parkin, G.F. and Owen, W.F. (1986).

APPLICABILITY

Type of wastewater

Anaerobic lagoons are used for treatment of industrial wastewaters, mixtures of industrial/domestic wastewaters with high organic loading, and as a first stage in municipal lagoons. Typical industries include slaughterhouses, dairies, meat/poultry-processing plants, rendering plants, and vegetable processing facilities.

Typically, anaerobic lagoons are used in series with aerobic or facultative lagoons, enhancing the operation of both types of lagoons as aerobic or facultative lagoons providing further treatment of the effluent. Initial treatment in an anaerobic lagoon often renders the waste more amenable to further treatment and reduces the oxygen demand.

Anaerobic lagoons often are used in small or rural communities where space is plentiful but costs are a concern. Low construction and operating costs make anaerobic lagoons a financially attractive alternative to other treatment systems, although sludge must occasionally be removed.

ADVANTAGES AND DISADVANTAGES

Some advantages and disadvantages of anaerobic lagoons are listed below:

Advantages

More effective for rapid stabilization of strong organic wastes, making higher influent organic loading possible.

Produce methane, which can be used to heat buildings, run engines, or generate electricity, but methane collection increases operational problems.

Produce less biomass per unit of organic material processed. Less biomass produced equates to savings in sludge handling and disposal costs.

Do not require additional energy, because they are not aerated, heated, or mixed.

Less expensive to construct and operate.

Ponds can be operated in series.

Disadvantages

Require a relatively large area of land.

Produce undesirable odors unless provisions are made to oxidize the escaping gases. Gas production must be minimized (sulfate concentration must be reduced to less than 100 mg/L) or mechanical aeration at the surface of the pond to oxidize the escaping gases is necessary. Aerators must be located to ensure that anaerobic activity is not inhibited by introducing dissolved oxygen to depths below the top 0.6 to 0.9 m (2 to 3 feet) of the anaerobic lagoon. Another option is to locate the lagoon in a remote area.

Require a relatively long detention time for organic stabilization due to the slow growth rate of the methane formers and sludge digestion.

Wastewater seepage into the groundwater may be a problem. Providing a liner for the lagoon can prevent this problem.

Environmental conditions directly impact operations so any variance limits the ability to control the process, (e.g. lagoons are sensitive to temperature fluctuations).

DESIGN CRITERIA

The design of aerobic lagoons is not well defined and a widely accepted overall design equation does not exist. Numerous methods have been proposed, but the results vary widely. Design is often based on organic loading rates and hydraulic detention times derived from pilot plant studies and observations of existing operating systems. States in which lagoons are commonly used often have regulations governing their design, installation, and management. For example, state regulations may require specific organic loading rates, detention times, embankment slopes (1:3 to 1:4), and maximum allowable seepage (1 to 6 mm/d).

Optimum performance is based on many factors, including temperature and pH. Other important factors to consider include:

Organic loading rate

Typical acceptable loading rates range between 0.04 and 0.30 $kg/m^3/d$ (2.5 to 18.7 lb $BOD_5/10^3$ ft^3/d), varying with water temperature.

Detention time

Typical detention times range from 1 to 50 days, depending on the temperature of the wastewater.

Lagoon dimensions

Because anaerobic lagoons require less surface area than facultative lagoons since the oxygen transfer rate is not a factor, their design should minimize the surface area-to-volume ratio. Typical surface areas range from 0.2 to 0.8 hectares (0.5 to 2 acres). The lagoon should be as deep as practicable, as greater depth provides improved heat retention. A depth of 2.4 to 6.0 m (8 to 20 feet) can be used; however, depths approaching 6.0 m (20 feet) are recommended to reduce the surface area and to conserve heat in the reactor (lagoon). The lagoon should be designed to reduce short circuiting and should incorporate a minimum freeboard of 0.9 m (3 feet).

Construction of lagoon bottom

Groundwater seepage may be a concern. The lagoon should be lined with an impermeable material such as plastic, rubber, clay, or cement.

Control of surface runoff

Lagoons should not receive significant amounts of surface runoff. If necessary, provision should be made to divert surface water around the lagoon. Table 3 summarizes general design criteria for anaerobic lagoons.

PERFORMANCE

System performance depends on loading conditions, temperature conditions, and whether the pH is maintained within the optimum range. Table 4 shows expected removal efficiencies for municipal wastewaters. In cold climates, detention times as great

TABLE 3 DESIGN CRITERIA

Criteria	Range
Optimum water temperature (C):	30 - 35 degrees (Essentially unattainable in municipal systems)
pH	6.6 to 7.6
Organic loading:	0.04-0.30 kg/m^3/d (2.5 - 18.7 lbs/10^3 ft^3/d ((temperature dependent)
Detention Time:	1 to 50 days (temperature dependent)
Surface Area:	0.2 to 0.8 hectares (0.5 to 2 acres)
Depth	2.4 to 6.0 meters (8 to 20 feet) (depths approaching 6.0 meters [20 feet] preferred)

Source: Metcalf & Eddy, Inc., 1991.

as 50 days and volumetric loading rates as low as 0.04 kg BOD_5/m^3/d (2.5 lbs/10^3 ft^3/d) may be required to achieve 50 percent reduction in BOD_5. Table 4 shows the relationship of temperature, detention time, and BOD reduction. Effluent TSS will range between 80 and 160 mg/L.

The effluent is not suitable for direct discharge to receiving waters. Lagoon contents that are black indicate that the lagoon is functioning properly.

OPERATION AND MAINTENANCE

Operation and maintenance requirements of a lagoon are minimal. A daily grab sample of influent and effluent should be taken and analyzed to ensure proper operation. Aside from sampling, analysis, and general upkeep, the system is virtually maintenance-free. Solids accumulate in the lagoon bottom and require removal on an infrequent basis (5-10 years), depending on the amount of inert material in the influent and the temperature. Sludge depth should be determined annually. Table 1 depicts optimum and extreme operating ranges for methane formation. Rates outside of these extreme ranges will decrease the rate of methane formation.

TABLE 4 FIVE-DAY BOD REDUCTION AS A FUNCTION OF DETENTION TIME AND TEMPERATURE

Temperature (deg. C)	Detention time (d)	BOD reduction (%)
10	5	50
10-15	4-5	30-40
15-20	2-3	40-50
20-25	1-2	40-60
25-30	1-2	60-80

Source: World Health Organization, 1987.

COSTS

The primary cost associated with constructing an anaerobic lagoon is the cost of the land, earthwork appurtenances, required service facilities, and the excavation. Costs for forming the embankment, compacting, lining, service road and fencing, and piping and pumps also need to be considered. Operating costs and power requirements are minimal.

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Other Related Fact Sheets

Other EPA Fact Sheets can be found at the following web address:

http://www.epa.gov/owm/mtb/mtbfact.htm

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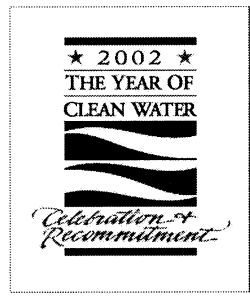

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Livestock Mortality Composting

FOR LARGE AND SMALL OPERATIONS IN THE SEMI-ARID WEST

MONTANA STATE UNIVERSITY EXTENSION

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Contents

Why Compost Animal Mortalities?

Many livestock producers are concerned about proper mortality disposal and management. Proper management of animal mortalities on the farm/ranch has important implications for nutrient management, herd and flock health, as well as farm/ranch family and public health. The purpose of proper mortality disposal is to prevent the spread of infectious, contagious and communicable diseases and to protect air, water and soil quality. Also, there are legal issues and requirements related to nutrient management and the permitting of animal feeding operations. To best ensure human health and safety, reduce regulatory risks, and protect environmental resources, livestock producers should become familiar with best management practices (BMPs) for dealing with dead animals. They should also be aware of state laws related to proper disposal or processing of mortalities.

Disposal of routine operational mortalities and catastrophic mortalities must be defined in a comprehensive nutrient management plan. In addition, zoos and other facilities that house large animals (or many animals) may benefit from the techniques and resources provided in this manual.

Mortality composting is an increasingly popular and viable alternative compared to other disposal practices because of cost savings, reduced environmental risks, and the generation of a useful end-product. This manual is designed to provide livestock producers in Montana, Wyoming, Colorado, New Mexico and surrounding states with the knowledge, tools, and resources to develop a mortality management; with specific focus on the composting option.

Unacceptable Animal Mortality Disposal

Abandonment

Though dragging off a carcass to the "boneyard" has been a historic practice, abandonment is **strongly discouraged.** Abandonment is likely **illegal** in most states. Examples of abandonment include: carcasses abandoned on the surface, in open pits, ditches, water features and sinkholes or in wells. Abandonment promotes extreme biological and disease hazard, threats to water quality, odors, flies, scavengers, rodents, and visual pollution.

Methods of Animal Mortality Disposal

Burning

Disposing of animal mortalities by open pyre burning is discouraged. Most producers have difficulty finding proper fuel to maintain temperature and flame, and struggle to obtain complete consumption of the carcass or carcasses in a timely manner. Air emissions are uncontrolled and likely dangerous, depending on the fuel source. Burning should only be considered in emergency situations, and with proper advisement and permission from the appropriate regulatory agency.

Incineration

Incineration is a safe method of carcass management from a bio-security standpoint. Incineration is different from burning because when practiced correctly, the entire carcass is quickly and completely consumed by fire and heat. This practice must be done in an approved device with air quality and emissions controls. Incineration is primarily utilized for disposing of small carcasses (such as poultry). The cost of fuel may limit adoption of this practice because it can be an energy intensive process.

Burial

Burial is probably the most common method of dead animal disposal, although some states have outlawed it. Most states have regulatory burial guidelines outlining site location, distance from waterways, depth to groundwater, etc. If proper procedures are used, burial is safe; however, certain portions of carcasses can persist for years in an anaerobic (low oxygen) environment and there is no assurance of pathogen reduction. During construction projects on former poultry farms, old burial pits have been discovered that contain intact birds. Sites with a high water table and sandy soil do not allow proper depth or cover of burial without threatening ground water. Burial pits are considered mass graves and, if not managed properly, may pose additional risks through the spread of disease and other environmental contamination.

Land Filling

Disposing of carcasses at a licensed landfill is considered an acceptable method of burial. Land filling may be an option in some areas; however, the legality of this will be based on the classification of the facility, local regulations, and the policy

of the individual site. Even if the landfill is classified to accept carcasses, the management must also grant permission. It is a good idea to have a written agreement with the landfill service if you plan to regularly use this method of disposal. Drawbacks to landfill disposal may include additional handling of the mortality, transportation and tipping fees, and potential disease transmission.

Rendering

Rendering is a heat-driven process that takes place at a special facility in which waste animal tissue is separated and converted into value-added materials. Rendering is a relatively simple method of mortality management for the farmer/rancher, and it leaves no lasting legacy on the farm. However, there are very few rendering facilities across the U.S., and there are often fees associated with a rendering service. This is a recommended practice for those with access to a rendering service. The cost of rendering should be weighed against time management, input cost, and possible bio-security breaches when compared to other available methods. Local livestock or poultry producers and Extension staff may be the best resource for determining if this service exists in your area.

Livestock Mortality Composting

For many species, carcass composting (i.e., the biological process of converting organic matter into fine-particle humus-like material) is an environmentally preferable method for managing mortalities. When performed correctly, the end-product may be reused in future mortality composting, and under certain conditions, applied to animal feed crops and forest crops. Poultry composting is a common practice and much information is available that describes how to dispose of birds in this way.

Composting is practical for larger carcasses. Many operations, even in cold climates, successfully compost larger stock including sows, cattle and horses.. Composting large carcasses can save labor and land. This practice allows a dedicated area to be used and reused for carcass management; it is done above ground, thereby reducing the number of labor-intensive burial pits created as well as minimizing the number of buried carcasses on the property.

Technical procedures on composting cattle carcasses are available and continue to be studied and refined; this appears to be a viable option which will be described further in this manual. Most composting requires storm water protection, and possibly covering. Additional management and monitoring is required to refine the process, maintain temperatures, attain proper decomposition and prevent scavengers. Nutrients and organic matter in finished carcass compost can benefit forest and crop land; however, nutrient management guidelines should be followed.

Composting Principles

Composting is the “managed, biological, oxidation process that converts heterogeneous organic matter into a more homogeneous, fine-particle humus-like material” (Field Guide to On-farm Composting, 1999). This definition includes many important principles that need to be considered when composting.

Managing a compost pile can really be viewed as “farming microorganisms” to provide optimum conditions for the bacteria and fungi that do the real work of composting. The microorganisms need four things: carbon (C), nitrogen (N), water, and oxygen. Generally, the carbon and nitrogen need to be provided in balance, and we usually aim for a C:N ratio of about 30:1 at the beginning of the composting process. To achieve this, it is important to know the C:N ratios of your composting feedstocks (i.e., carbon materials such as straw, sawdust, animal bedding, etc.) and devise a good “recipe” or mixture. However, departure from this common wisdom for mortality composting will be discussed in this manual as C:N ratios exceed the recommendation (much greater carbon) when dealing with dead animals. Likewise, in the early stages of carcass composting mixing is not feasible.

As noted above, true composting must take place in the presence of air or “under aerobic conditions”. The bacteria and fungi that break down organic wastes in the pile require oxygen to achieve a compost end product. If oxygen is inadequate due to high moisture levels, waste will still

degrade, but it will degrade by rotting or fermenting rather than composting.

Water and oxygen also have to be provided for the microorganisms and are related to each other. If the compost is too wet, the oxygen levels will be too low. In most composting scenarios best success is attained with a moisture level at about 50 percent. The moisture content can be determined by weighing a sample, drying it and then reweighing, but it can also be estimated from a "squeeze test." Just squeeze the compost mix in your hand. It should be wet enough to stay together in a ball, and you should only be able to squeeze a little trickle of water out in between your fingers. To achieve this moisture level, watering and shaping the pile to accept moisture is often necsary.

The oxygen content in a compost pile should be about 5-20 percent. Some operators purchase hand-held oxygen meters to periodically measure that level. A drop in compost pile temperature after the start of the process is often a sign that there is an inadequate level of oxygen. Turning the pile is a management practice that is commonly used both to mix the ingredients and to add oxygen into the pile. The use of bulking material (a coarse-textured organic waste like wood chips) also aids in aeration of a compost pile. Turning should only be done after the active stage of composting for poultry you can turn after two to three weeks, for large livestock generally three to six months.

Though composting of medium to large carcasses and land applying the material is proving to be feasible, careful consideration must be given for goats and sheep due to the prevalence of scrapie, a prion disease, in flocks across the U.S. This disease is a transmissible spongiform encephalopathy (TSE) similar to BSE (i.e., mad cow disease) and the human Creutzfeldt-Jakob disease. If compost from diseased animals were used as fertilizer, it would create a serious bio-security threat. Fate of compost from sheep and goats should be carefully considered. Be sure to seek expert advice prior to disposal of these species. If a producer has a certified scrapie free flock, then they could proceed with practice in relative safety.

Incorporating Animals into the Composting Process

Influence of Animal Size

Size and volume of mortalities will directly influence the physical footprint of the pile or volume of bin space designed, amount of carbon material required, and the time required to fully compost the carcass(es). Smaller carcasses have more surface area relative to mass; this provides for more carbon material to carcass interaction. Similarly, cutting or breaking apart large carcasses can speed up the composting process, if necessary. While properly constructed and layered poultry mortality compost will process in a matter of a few short weeks, cattle will take months (6-12) under average conditions (in static piles; i.e., no turning).

Bones remaining at 3 months, skull on left, spine on right. These will nearly breakdown completely when recovered for 3 more months, credit: Schauermann

Preparation and Placement

For larger livestock, the carcass should be laid on its side on the middle of the base material with the body cavity opened and the rumen punctured for cattle, sheep and goats. This is done to prevent bloating and bursting which will displace cover and result in additional odor and nuisance. The carcass

should be covered completely with material on all sides (as described in the next section). The finished pile may reach up to six feet in height, in the example of a large cow. Small carcasses should be layered and arranged to maintain carbon margins around each dead animal. Small carcasses can also be stacked in tiers with carbon layers in between.

Calves on base, credit: Dafoe

Cows on base, credit: TX A&M Agrilife Extension

Base and Cover

Considering that a large carcass is very high in moisture and nitrogen, adding too much carbon likely will not be a threat to composting success. In the case of mortality composting, proper pile construction will result in gross C:N, considerably higher than the common 30:1 ratio and this does not appear to inhibit composting of large carcasses. Moisture distribution will be uneven throughout the pile and there are likely to be pockets of anaerobic decomposition immediately around the mortality. While much of the external carbon does not interact with the composting center, it serves a larger role in biofiltration and insulation. The extra carbon material is also valuable in absorbing excess moisture from the mortality. Conventional turning and C:N balance comes into play at the end of this process, weeks after the mortality has been consumed by the process.

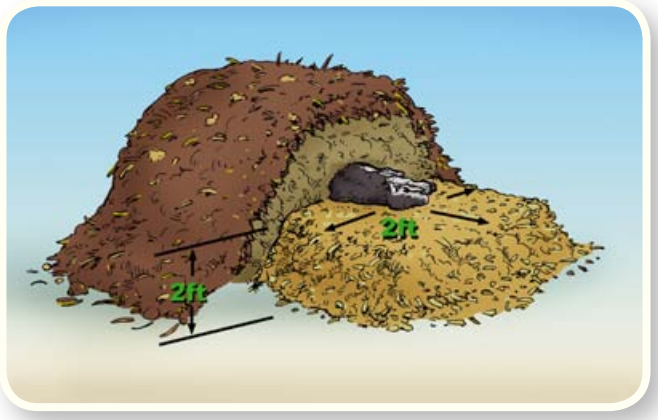
Anecdote: **Winter Tip –** surrounding the carcasses in warm or active compost will give them a quicker start, especially for winter or early spring mortalities. In Montana, producers have been successful with attaining necessary temperatures by placing non-frozen carcasses in the pile and building the core with silage, warm compost or manure solids. The pile should always be capped with a "clean" material such as sawdust or chopped straw. Likewise, getting carcasses started in compost before they freeze in the field helps the pile attain and maintain desirable temperatures.

Successful composting of mortalities has been reported with base thicknesses between 12 to 24 inches. The base should be comprised of a material that is both absorbent and bulky, such as wood chips and shreds with sizable pieces being 4 to 6 inches in length. This composting material is important for achieving satisfactory porosity for aeration. Material that packs tightly or is excessively wet is not recommended. The base material should not be excessively dry but moist like a damp, wrung-out sponge. To save time, always have a couple bases ready to accept animal mortalities. The carcass can be placed once a satisfactory base is established.

Core material can now be placed around the mortality. This is an opportunity to use a variety of materials found onsite or regionally. Please refer to Table 1 for a list of materials that have been used in the Rocky Mountain region. The material added directly around the sides and top of the carcass does not need to be as porous as the base; also, if the carbon source has some odor associated with it, the core around the carcasses is the ideal place for its use. Manure, silage, and other active materials, with a low C:N ratio may be ideal for this layer. Finally, the cap may also be a finer material than the base, and should be low odor carbon. Core and cap materials such as silage or moist sawdust in the 50-60 percent moisture range are ideal. The addition of the cap should bring the final margin around the carcass to a range

of 18-24 inches, as illustrated below. Estimates of total material needed to fully compost a full grown cow are 12 cubic yards, or for 1,000 lbs of carcass, 7.4 cubic yards (200 ft^3). The difference in the estimates can be attributed to the thicker base recommended by some experts. Practically speaking, for a mature cow, a proper base will be about 9 feet wide by 10 feet long. Once the mortality is placed in the middle of the base, 24 inches of cover in all directions should be attained. Considering side slope, material on top will likely be more than 24 inches above the mortality to achieve the proper margin. When layering smaller carcasses, or parts of carcasses, an 8 to 12 inch margin should be maintained around each carcass. Bins and bunkers can reduce height and foot print of piles.

Layered small carcasses, credit: Cornell Waste Management Institute



Cow position in pile, credit: Cornell Waste Management Institute

Carbon Options

Table 1. Unique or locally utilized carbon materials of the Rocky Mountain corridor; sources, pros, and cons of each. Ideal pile construction will have coarse material base, with other materials in core around carcass(es) and an inert material for a cap such as sawdust or compost.

Material	Source(s)	Pros	Cons
Fruit wastes	Orchards, vineyards, wineries	For core; may need to be mixed w/ drier material	Very wet (60-90% water)
Chile skins	Chile processors	Bulking agent	excess water directly from processor, nuisance factor
Cotton gin waste	Cotton gins	Aerates well, holds moisture, good pore space	Hauling costs, varies by region, 14:1 C:N
Garment processing fibers	garment processor	46:1 C:N	Wet product, hauling, very poor pore space
Paper mill waste	pulp and paper plants	95:1 C:N	Distance
Pecan cleanings	pecan processors	Bulking agent	Possible odor issues
Pecan trimmings	pecan farms	Bulking agent	Post processing

Bin and base, credit: Dafoe

Table 2. Most commonly used carbon material in the Rocky Mountain Corridor; sources, pros, and cons for each. Ideal pile construction will have coarse material base, with other materials in core around the carcass material and an inert material for a cap such as sawdust or compost.

Material	Source(s)	Pros	Cons
straw & hay (common)	local farms, onsite, zoos	availability	compresses, pore space diminishes quickly; C:N 17:1
hay (alfalfa)	Local farms, onsite, zoos	availability	compresses, pore space diminishes quickly;12:1 C:N
wood chips	timber mill, inert landfill, municipal yard waste, beetlekill	good pore space, especially for base of pile; 300:1	may be expensive
saw dust	timber mill, wood based industry, beetlekill	good cap material for odor control, green saw dust has good moisture for composting; 300:1	may be expensive
compost	onsite, compost distributors	active material, best for core	low pore space
manure (various species)	onsite	active material, best for core	odor, leaching potential, low pore space
horse manure	racetracks, boarding facilities	45:1 C:N	Low pore space, limited by region
separated manure solids	neighbors, onsite	active material, best for core	may still be too wet
silage	onsite	active material, best for core; 40:1 C:N	odor, leaching potential, low/medium pore space
grain residues/hulls	local mills/granaries	best for core	low pore space, oil seed residues may lead to odors
waste feed	onsite, feed lanes, storage	Active material	Possible odors, variable composition
cull potatoes	Potato farms	Best for core; could be mixed with dry material	High moisture (~80%)
biosolids	City waste management companies, municipalities	Good N source	Possible heavy metals, pathogens
yardwaste	Homeowners, landscape companies, municipalities	Can be good for base or cap	Variable C/N ratio and irregular flow; 15:1 C:N; potential trash

Windrows, Wooden Bins, or Hay Bale Bins/Bunkers—Footprint and Sizing

As previously mentioned, the size of a compost pile can be reduced through the use of bins or bunkers. Windrows and piles will have the largest physical footprint and may pose the greatest attraction to scavengers if the area is not appropriately fenced. The use of some type of structure to contain the area and reduce physical footprint is recommended. This also provides visual screening. This decision will also be based on carcass size and volume of mortality. Temporary bins may be constructed by arranging hay bales to contain the compost. Permanent, slatted wooden or metal walls can also be constructed for large carcasses, though it represents a greater expense. However, windrows and piles will offer the best passive air flow to the sides of the materials.

Poultry carcasses are commonly composted in wooden bins under the roof of specially designed litter stack houses. Large square hay bales can be placed around the pile's perimeter to exclude pests and absorb any possible run-off. Round bales can be used for building a retaining wall around the pile (figure #); for small ruminants, pigs or other stock, bins could be built with small square bales. Temporary fencing or stock panels can be used to bar the front of the mortality compost bin and exclude nuisance and scavenger animals. Carcasses should remain completely covered throughout the process.

Monitoring and Management

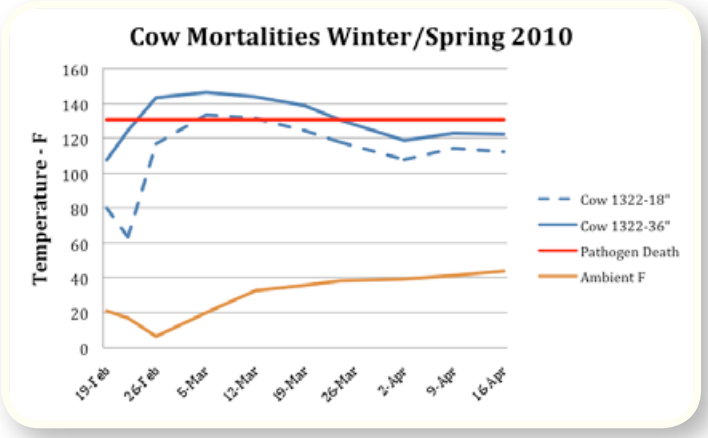
Composting

Now that the mortality are properly enveloped or incorporated the process of composting takes 4-12 months depending on mortality size and mixture. During this phase it is a good practice to monitor your piles and intervene at the appropriate times, i.e.: when additional cover is needed or pile is emitting odor. Some operations will leave marker where the last mortality is located to avoid accidentally disturbing the active site. The process of composting mortality is a passive process. This phase of the process should not be disturbed for three to six months depending on animal size. During this time microbial activity from bacteria and fungi are performing their function by reducing the carcass to a homogenous organic material. Most of the easily decomposed tissue is virtually "gone" within six weeks. Fungi need the extra time to continue working on the remains. The pile can be disturbed for mixing, watering and stockpiling for curing after four to six months in the passive phase.

Temperature

Temperature management is a critical component of successful composting. Monitoring involves both taking and recording the temperature of your compost piles and making observations about their condition. A long-stem thermometer inserted into the pile after construction is the first step in monitoring. Reaching thermophilic temeratures,120-150 F, assures the operator of pathogen destruction and effective composting. A compost thermometer has a long probe (18-60 inches long) in order to measure the internal temperature of a compost pile.

Temperature is an important indicator of how your compost pile is doing, because it is a reflection of the activity of the microorganisms that are doing all the work of composting material in the pile. When microbes feast, they multiply and give off heat. Thus, measuring temperature is a way to check-up on them to ensure that they are alive and functioning optimally. If temperatures are cool (<80° F), there is some reason why the microbes are not thriving. Temperature should be checked every couple days during the first week to 10 days after covering the mortality. Thereafter it is wise to check on temperatures at least weekly. Graph the temperature as a function of time and you'll see it rise quickly up to about 130-160° F and then decline gradually. Under normal composting conditions, when temperature declines for a week or more, it is time to turn the pile in order to aerate it. This typically results in mounting temperatures again, if conditions remain optimum. Temperatures in the 140 to 160 degree range, held for 48-72 hours are necessary to sterilize weed seeds and destroy pathogens.



However, when composting mortalities, the piles need to sit, undisturbed for a few weeks or months; temperatures will be quite variable during this time. Because of the high moisture content of a large carcass, there will be pockets of wet anaerobic degradation around animal; a proper pile will naturally correct this. Once the pile is turned it should be evaluated for water content (see below) and temperatures tracked for another month. Times in the Rocky Mountain west to achieve this status may range from four to eight months. This final period after turning should continue composting prior to curing. Bones will continue to break down in this phase, which follows more traditional composting recommendations.

Moisture Content

You can use the squeeze test described previously to evaluate whether your compost piles in the post-turning final stage have adequate moisture. If piles entering the final stage do not have enough moisture, the best time to add water is at the time of turning. In static piles (the beginning stage of mortality composting), turning and watering do not typically take place unless there is a problem (lack of temperature rise, for example). Because of this, it is even more important to get the moisture content right from the start. Moisture of 50-60 percent in the carbon based compost materials is ideal. If necessary, add water to the compost material you are using to bury the carcasses in a few days prior to or on the day you start the carcass composting (prior to adding the cap). The cap will reduce evaporation from the piles and help to maintain optimum water levels.

Moisture Management

If carbon is very dry, add moisture to the layers as you are building the pile. The compost feedstock should be at 40- 60 percent moisture (this has proven to be a good range for arid climates). Piles/ windrows can be shaped to shed moisture or include it depending on climate and weather conditions. Piles with peaked tops will shed moisture in high precipitation areas. Creating a flat top will allow moisture that falls on the pile to soak in. Creating a trough will allow moisture to collect and soak in. When piles are working efficiently it is hard to add moisture, as much of it is released into the atmosphere.

Other

In addition to temperature and moisture content, it is important to monitor your piles regularly for scavenger activity, odors, and flies. These issues are addressed in the *Issues* section of this document.

Curing and Storage

Curing is the stage of composting that occurs after the thermophilic (hot) process has ended and mesophilic (warm) conditions are established. Curing usually takes place by simply allowing the compost to sit for an additional period of time on-site. Winter conditions can potentially prolong this phase of the composting process because very cold conditions may prevent adequate microbial activity.

There must be sufficient aeration and moisture during this phase as oxygen loving organisms are at work to further breakdown the organic material. Anaerobic conditions can still occur so it may be necessary to turn or mix the pile during this phase. Curing also gives organisms more time to breakdown some of the larger bones to a more brittle and smaller form that is easier to incorporate into the soil. Bones can be screened out of compost that will be land applied, or introduced into new piles to continue breaking down. There should not be a large increase in temperature after this mixing but some increase in temperature is expected and is a good sign of microbial activity and the curing phase is underway. Observe the pile temperature after mixing with

a long-stem thermometer to assure the pile is proceeding according to plan. The pile should be left for another 4 to 8 months. By this time very few bones will remain visible, large bones will be brittle, and the material can be appropriately used. Screening before land application will avoid large bones from being applied to the ground.

Storage of compost increases the size, or footprint, of the composting site. However, it is a necessary component to the system that provides maximum flexibility in the end use of the material. Compost should only be stored within the protected composting area after the curing phase when little to no risk of continued heating will occur. Slightly more storage area may be needed if active composting occurs during the winter months when potentially less mass is lost during composting as compared to summer. The goal with storage is keep it from becoming a nuisance but accessible for land application, or recycling into new mortality piles when the time is right.

Site Selection and Environmental Management

Good stewardship of the land means taking the necessary steps to prevent possible problems that could negatively impact water, air, and soil quality. Most states have regulations regarding management practices for handling wastes; often dependent on type of waste, and size or tonnage of the operation. However, best management practices are encouraged for all composting operations even if exempt from specific regulations. The information below can help identify some best management practices that should be considered.

Site Selection

When choosing an appropriate site for composting there is a variety of general characteristics that should be considered. An appropriate site will:

- Help to protect water and soil quality,
- Protect bio-security,
- Prevent complaints and negative reactions of neighbors,
- Decrease nuisance problems, and
- Minimize the challenges in operating and managing the composting operation.
- In addition, the location of the composting site should be:
- Easily accessible (in most weather),
- Require minimal travel,
- Be convenient for material handling, and
- Maintain an adequate distance from live production animals to help reduce the risk of the spread of disease.

Although specific site selection requirements may vary from state to state, the location should have all-weather access and allow for storage of co-composting materials, and should also have minimal interference with other operations and traffic. The site should also allow clearance from underground or overhead utilities for safe maneuvering of equipment.

Consideration of visibility and location of traffic patterns required for moving dead animals, adding amendments (i.e., co-composting materials), and removing finished compost. An adjacent storage area for compost materials (i.e., sawdust, straw, crop residue, etc.), will eliminate the need to transport amendments from a distance. In the arid west, moisture may be needed in the final composting steps, once the mortality has been consumed. Consider how you may get water to the site for this purpose.

A compost site should be located in a well-drained area (but not well drained soils) that is at least three feet above the high water table level, at least 300 feet from sensitive water resources (e.g., streams, ponds, wells, etc.), and that has adequate slope (one to three percent) to allow proper drainage and prevent pooling of water.

The base of the compost site should consist of soil with low permeability. If the predominant soils are well-drained and close to ground water, a compacted layer of sand or gravel about 15 cm (6 in) thick could be used. In some situations, a constructed concrete pad or imported clay

pad may be necessary. Seek local guidance regarding soil type, groundwater issues, and related management options. Engineered types of pads pay for themselves during periods of extreme weather conditions and are better than compacted sand or gravel. Similar recommendations would apply to where cured and finished compost is stored.

Runoff from the composting operation should be treated through a vegetative filter strip or infiltration area before it reaches a water resource. Diverting water away from the compost pile with a berm minimizes the amount of runoff generated by the compost site, especially in the arid west.

Composting areas should be located downwind of nearby residences to minimize potential odors or dust being carried to neighboring residences by prevailing winds. Although composting does not usually generate odors, regular handling and composting of dead animals may be offensive to neighbors.

Stormwater Management

Most states have recommendations or requirements for stormwater management, especially under permitted facilities. There are three basic principles to consider in site management regarding runoff: 1) prevention, 2) collection, 3) distribution. Preventing water from running onto the composting site helps keep the site manageable and is likely the law in many states. Orienting windrows (when used) perpendicular to the slope of the site allows the windrows to absorb moisture and prevents erosion in-between. Situate your compost site to avoid water ponding, and facilitate collection/movement of excess water to a buffer, filter strip or collection structure if the run-off will be significant. If a composting area uses a run-off collection pond, the effluent should be treated in accordance with the laws and best management practices associated with land application of liquid animal waste.

Big Rain Events—Permitting Issues, Applicable Rules

Big rains can bring big problems even for small operation. Adopting conservation practices that lessen the effects of big rains can decrease non-point source pollution of nearby streams or shallow groundwater, reduce impact of odors, and decrease the likelihood of the spread of disease or pathogens. The National Oceanic and Atmospheric Administration has developed different time scale maps for storm events such as the 24-hour, 25-year precipitation maps that can help with planning. USDA-NRCS can also assist with assessing conservation practice needs for the area that would produce runoff (http://hdsc.nws.noaa.gov/hdsc/pfds/index.html).

Dust Control

Evaporation generally exceeds precipitation, in the arid west, on a yearly basis; traffic in the composting areas may generate dust. Dust from soil can be avoided by maintaining a work area surface that is either compacted or uses a layer of compost or other carbon material that is not as prone to becoming airborne. A short-term fix to excess dust is to use water trucks with a water delivery system to moisten the work area. Otherwise, equipment traffic should be limited when conditions for airborne dust are favorable.

Take steps to be prepared for fires as well. Mistakes in moisture control can lead to fires at compost sites. The smoke can travel a very long way and can lead to nuisance complaints. Assuring that adequate water supplies are near the compost pile and having a fire intervention plan in place will make all the difference in managing the compost site. It is not advisable to water a compost fire; this starts a dangerous cycle that will actually lead to greater combustion potential. Instead, spread out the materials that are reaching high temperatures. You should not see temperatures in mortality compost much over 160 degree F. Charring and fire potential becomes serious when piles approach 180 degrees F.

Equipment Decisions

Since the goal of animal mortality composting is environmentally sound, labor-efficient disposition of animal carcasses and related waste, and not a fully functional comprehensive composting program for manure and other organic materials, equipment choices are easier to make. For a full discussion and overview of equipment for a comprehensive composting program, please reference: Compost Fact Sheet #7 from the Cornelll Waste Management Institute, "Compost Equipment" 2004/2005. At a minimum, carcass composting will require a front-end loader, but a probe thermometer and screen are also recommended.

A tractor with a bucket or skid-steer loader are imperative for building the pile or loading the bin, in addition to easily moving and placing larger mortalities. The size and number of carcasses to be encountered throughout the year will dictate the needed loader size. A poultry facility will obviously be able to utilize smaller equipment than a beef feedlot or dairy. A dairy may have up to eight percent operational mortalities throughout the year with Holsteins weighing as much as 1,400 pounds. Beef steers may be smaller, in the 500 to 1,000 pound range; sows on a hog operation can also be quite large, requiring appropriate sized equipment.

Probe thermometers will help in finishing the compost once the bulk of the carcass material is degraded. Reaching benchmark temperatures in the final product will help destroy pathogens and sterilize weed seeds. These temperatures are discussed in the *Composting Principles* section of this document. Probe thermometers are available in dial or digital format (insert picture analog dial thermometer). A 36" dial probe thermometer can be found at several agricultural and natural resource supply companies for under $100. They are often listed as "dial soil and compost probe thermometer." Digital versions are also available, at a higher price, and may be part of comprehensive packages that also measure oxygen and moisture.

A screen is also helpful in improving final product quality, especially if the compost will be land applied. A screen allows for the separation of compost fines from residual bones and other trash such as bailing twine, ear tags or other material. The simplest screen, ideal to have near the mortality compost site, is a frame of angle iron with an expanded metal face. The face should be angled at 45 degrees or more, and elevated one to five feet off of grade with the top of the screen appropriate to the reach of the loader being used. The width should also be relative to the width of the bucket on the operation's loader. For example, screen area should be five to six feet wide by six to eight feet long, angled and elevated as previously described. More discussion of bones and screening is found in the *Issues* section of this document.

Home-made screen, credit: Bass

Effect of Climate

Temperature and Precipitation

Composting can occur practically all year, even in the cold and semi-arid climates of the upper plains and Rocky Mountains. Winter temperatures usually slow the process down, and can prevent adequate initial heating. It has been documented in southern Canada to lower the amount of decomposition by 20 percent during the thermophilic (hot) and mesophilic (warm) stages of composting. However, research in Montana has shown temperatures at 18" and 36" deep in a mature cow compost bin to reach above 130 degrees F within days of start, even during winter conditions. As previously mentioned, some tips for mitigating ambient temperature affect include: incorporating the carcass before it freezes, using an active material (silage, manure solids, warm compost) around the carcass and core of the pile, and capping the pile with extra insulating material such as sawdust. The curing stage is often slowed by extremely cold conditions.

Though carcass moisture will be sufficient to start the process, proper moisture in the co-composting materials (carbon sources) is also important. Fresh or green sawdust and shavings are excellent. The arid western climate can inhibit complete composting and curing. After several weeks (or months) of static composting, the pile should be turned and watered to finish off the process moving into the curing phase. Warm weather increases the amount of water that is lost to evaporation; curing piles should be monitored more closely to assure adequate moisture, assuring that sufficient microbial activity can occur during this phase of the process.

While much of the northern plains and Rocky Mountains are dry for most of the year, there are periods when moisture can become excessive. Excess moisture is not so much an issue with the piles themselves but with traffic lanes and carbon sources. Carbon sources should be properly stored or covered if precipitation could saturate them. Carbon sources in the previously mentioned 40-60 percent moisture range are very ideal for mortality composting and continue to absorb moisture, preventing leaching. Excessively dry compost piles will actually shed water for a time before they begin to absorb moisture. Snow does not seem to affect the pile and may serve as an insulating blanket during periods of extreme cold. Bad weather, of course, can increase mortality and base piles should be constructed ahead of time in expectation of weather-related deaths.

Snow on pile/bin, credit: Dafoe

Issues To Watch Out For

Bones

Bones and miscellaneous trash can impact quality of material for end use, especially if moving off-farm. Shards of un-degraded large bones such as long leg bones and hip girdles can even puncture tires on farm equipment. Therefore, screening is advised to remove bones or other trash from the compost. Bones may be reincorporated to new mortality compost piles, for further break-down; residual bone can be used in the base of a new pile adding pore space for air circulation.

Small vs. Large Operations: Issues of Scale

A primary issue with scale will be selecting the site and sizing the area dedicated to mortality composting. General site recommendations are previously covered in the *Site Selection* section of this document; however, sizing for a small livestock operation will be different than a large dairy. Consider the operation's operational mortalities. A single large cow may require a compost pile with a base of 10 by 12 feet if not contained in a bin or bunker of some sort, whereas one could compost several small animals in the same space. Likewise, the amount of carbon material needed to incorporate large carcasses will be greater for more and larger animals. This is discussed in the *Incorporating Dead Materials into the Carbon Process* section of this document. Finally, scale affects equipment selection, such as the size of a loader or tractor needed to haul, lift into place, and cover mortalities with material. Equipment selection is discussed in the *Equipment Decisions* section of this document.

Scavengers

Proper coverage and capping of mortality compost piles is vital to discouraging scavengers. Also, fencing around mortality compost is advisable for the same reason. At two sites in rural Montana with known dog and coyote populations, little to no scavenger activity has been noted. In some areas, the practice of composting, in general, should be carefully considered and protected in order prevent attraction of dangerous scavengers such as grizzly bears.

Odors

Properly managed compost, even mortality compost, should not produce great odor. Some materials available for composting may cause more odor than the mortality itself. This may be the case with silage, manure or some crop residues, especially oil seeds or spoiled feed. An adequate cap on the pile of inert material such as sawdust or finished compost will help reduce, if not eliminate, odor.

Nuisance

The greatest nuisance associated with mortality compost is likely to be flies and other insects. Additionally, longer term compost piles may harbor noxious weeds whose seeds are introduced to the pile by carbon materials used or from the surrounding environment. Moisture and temperature will play a role in managing both. High moisture can lead to better breeding for flies. Turning the compost towards the end of the process and allowing re-heating to around 140° F after the bulk of the carcass is degraded will help sterilize most weed seeds. An overall weed control program and knowledge about the carbon sources will also help control this potential problem. Herbicides used on or near compost, or on source materials can persist in the final product. Therefore, their use should be carefully considered.

Neighbor Relations

Proper management of the previously listed issues is important for neighbor relations. While it is discussed in this publication that mortality compost sites should have good all-season access, they should also be visually screened from public roads and neighboring properties. Likewise good management practices to prevent scavengers from distributing carcasses, prevention odors, and reduction of flies and nuisances are all imperative for maintaining good neighbor relations.

Prion Diseases and Composting

This science on this issue is still inconclusive; composting suspect animals should be avoided. Prion diseases, such as scrapie (sheep), chronic wasting disease (CDW; deer and elk) and bovine spongiform encephalopathy (BSE; cattle), are diseases that cause a degeneration of the central nervous system. Prion diseases appear to be extremely durable in the environment, likely because of their ability to bind with soil minerals. For example, in an experiment, scrapie remained infectious after burial in garden soil for three years and anecdotal evidence suggests that the disease persisted for 16 years in an abandoned sheep barn.

One recent study suggests that composting may have the potential to degrade the part of the protein responsible for causing infection, called PrPSc. In this study, the PrPSc in samples of scrapie-infected sheep tissues (i.e., central-nervous-system, lymphoid system, and various organs) experimentally composted in a static-pile passive-aeration system were demonstrated to have degraded after 108 days; however, this study did not specifically measure infectiousness of composted tissues.

Another study, which simulated a natural scenario in which an infected animal dies and remains at ordinary physiological and ambient temperatures, indicated that the N-terminus of brain-derived PrPSc, a section of the protein vulnerable to cleavage, was lost after 7-35 days(3). While this study demonstrated that PrPSc can be degraded in certain environmental conditions, it did not determine the infectivity of the resulting, damaged protein.

Based on this recent work, it appears that composting conditions that include high heat and bacteria may degrade PrPSc, but that these conditions are not typical of natural environments. The risk of disease transmission appears to be most heavily influenced by the degree of by-pass, which is the compost that does not reach critical temperature because of its location in the pile. A United Kingdom investigation of BSE concluded that composting and compost spread on pasture were safe when a 2-tier (primary and secondary) composting system was used together with a 2-month grazing ban for the treated pasture.

Because prion diseases are transmissible between mammalian species, are incurable, and are highly infectious, extreme caution should still be used when disposing of infected carcasses. Incineration and burial in landfills, practices often used to dispose of infected carcasses, may create air and water contamination risks and may be publically unpalatable. Certification of flocks for scrapie free status can be done and may open up composting as safe mortality management tool.

Compost Quality, Use and Other Considerations

Mortality Compost Quality and Use

The practice of mortality composting has been explained in this document as an alternative to other management methods. There are environmental and financial benefits to the practice compared to alternative disposal methods and composting may result in value added product. Mortality composting has also been discussed here as a stand-alone process and not necessarily part of a larger compost business that may also be related to the livestock or poultry operation. At this time, *mortality* composting should be considered a management option and not something that would be highly marketable. This is especially true where there are other composting operations going on. The benefits are reaped from use on-farm.

Mortality compost is finished when the soft tissues, odors, and most of the bones are no longer present in the bins, piles or windrows. Since safe animal disposal is the goal, the compost quality would not necessarily be that of retail quality compost. Large bones and fragments can persist, as well as vet waste, implants, ear tags or other non-degradable materials. The appearance of these items in material sold or given away could be a liability against the producer. Finally, even with well-managed mortality composting, there is a possibility that not all pathogens were destroyed. Even if cause of death was not known to be the result of disease, exporting mortality can be a great bio-security risk (please see *Prions* section, particularly if you are considering composing of small ruminants).

The best recommendation for use of mortality compost is to re-incorporate it into the mortality management process. Finished compost can be used for core and cap, though old exposed bones may attract unwanted attention. Reusing the compost in this manner will continually break down residuals from the last batch and often help jump-start the next mortality pile. If this compost is land applied, it should be used carefully on the producer's property. As a final precautionary measure, avoid using mortality compost on crops or plants such as vegetables that are for direct human consumption. Have the material tested for nutrient value before using it as fertilizer or a soil amendment.

Emergency Situations

Emergency Response Plan

All livestock operations need to have an emergency response plan (ERP, sometimes an emergency action plan {EAP}) developed that describes how to deal with catastrophic mortality loss. This is also a requirement in nutrient management plans for permitted animal feeding operations. Local Emergency Management Coordinators and County Extension Agent should be consulted prior to developing that plan, as they have access to resource materials and are acquainted with the local, state, and federal officials who will need to be contacted following a catastrophic mortality event. In addition, in many major livestock production areas, the Emergency Management Coordinator will have already developed an ERP for the county that a livestock operation may be able to "piggyback" onto.

Catastrophic Mortality Loss

Routine mortality losses are relatively simple to deal with. However, a livestock operation may encounter a catastrophic mortality loss at some point. In this situation, a producer is faced with the death of many animals as a result of one incident or event. Some examples could be a barn fire, flooding, tornado, ventilation failure in a building, poisoning, animal disease, heat stress, or a blizzard.

Carcass disposal following a catastrophic mortality loss can be a daunting task and may pose a unique set of issues. Typical carcass disposal regulations are designed with the intent of routine on-farm losses, where as one or two animals are lost from time to time. A catastrophic mortality event may require disposal of more animals than what current regulations will allow. Therefore, special permitting may be required. In addition, the circumstances of death may require that the mortalities be disposed of in a specified fashion. As an example, if a large number of cattle are poisoned; those animals would not be disposed of via a rendering service; as there could be potential of contaminating pet foods.

Having an ERP in hand will speed the response to catastrophic losses and do so in a fashion that will hopefully help to limit liability and public health and safety concerns. Often times a catastrophic mortality loss is the result of a major news event, such as a tornado striking a community including five beef cattle feedlots. The ability to quickly and efficiently execute a well planned, environmentally friendly, humane, and health conscious response can help avoid poor public perceptions and negative press.

Many of the people tasked with responding to a catastrophic mortality event have expressed a preference for composting, especially when the land space and resources are available. When proper precautions are taken, composting can help protect water quality and air quality when compared to mass burial or incineration.

High Water Events and Your Compost Pile

Compost piles, no matter how they are constructed, should never be situated in a flood plain. Should a heavy water event occur, the compost operation should be inspected as soon as possible, to ensure that erosion of the compost has not occurred. Damaged compost piles may require reforming or even complete reconstruction. Although rare in the Rocky Mountains, for areas that receive more than 40 inches of annual rainfall, it is recommended that compost bins/pits be covered by a roof if possible.

Tornado/High Winds and Your Compost Pile

Tornados and/or excessively high winds may cause damage to a compost operation. Following high-wind events, compost piles should be inspected to determine if recovering or reforming of the pile is necessary. In addition, in some cases carcasses may have been removed from the compost and transported elsewhere by a tornado. In this type of situation, the local Emergency Management Coordinator should be contacted and informed in order to manage any possible public health risks.

Economics of Livestock Mortality Disposal

Mortality Composting, a Viable Option

Mortality composing is becoming a viable option for many farmers and ranchers out of sheer economic necessity. For many years, rendering services were the preferred choice for disposal of animal mortalities and, in many cases, is still a preferred method if the price is right. However, these services have become so few and far between that their fees are usually too expensive to justify. As in any enterprise, necessity and expense are great incubators of invention. This turn of events, along with an improved understanding of composting principles, have led many to turn to composting as a viable alternative for disposal. As composting practices have become more widely researched and implemented, they have emerged as a viable and economically smart solution for livestock operations interested in an alternative to expensive processes such as rendering, incineration, burning and land filling.

Equipment and Facility Needs

The equipment required to conduct composting on an individual operation will vary with size of operation and volume of mortality losses. In general, many medium to large operations may already have the needed equipment. A front-end loader with capacity to move the types of carcasses encountered, and composting material, will serve basic equipment needs for most operations. Those also composting manure or other materials in windrows have specialized equipment dedicated exclusively to composting activities. The cost of a new commercial compost turner or windrow machine may range from $30,000 in excess of $100,000. Although used equipment and leases are available; this type of equipment is not necessary for mortality composting, and not recommended for bin and single pile composting. A fuller discussion of equipment is included in the section titled "Equipment Decisions."

Facility needs for a successful composting operation primarily includes open space to place windrows of composted material. This space should be sufficient to place windrows of composted material for a period of at least six months without need to remove. Sufficient room to maneuver equipment in and around compost windrows is also necessary. A complete discussion of site and facility needs is included in the section titled "Site Selection."

Making the Decision

The decision to move away from conventional disposal methods and towards mortality composting requires some thought into the benefits and costs of such a change. All producers can use the partial budgeting principle to compare various benefits and costs associated with making a change in their mortality management procedures. This process will help producers visualize the potential savings and/or costs of one method over another in real numbers.

The partial budget form provided in this manual is designed to help produces look at adjustments in a portion of any business enterprise and evaluate whether it is a desirable option. Because partial budgeting only looks at incremental changes that come with a change of business practices, only the items specific to the decision are considered.

Key to the process of partial budgeting is the concept that changes in a business will result in one or more of the following: additional returns (+), additional costs (-), reduced costs (+), and reduced returns (-). As designated by the +/- symbol behind each of these results (Figure 1), offsetting effects of positive and negative result in a final result when all figures are totaled. If the net result of the above figures is positive, the change is thought to be positive to the bottom line of the business.

Partial Budgeting and Avoided Cost

Partial budgeting is a form of budgeting that looks at potential changes in an operation to gauge whether the proposed change(s) would be a benefit to the profitability of the enterprise. While many portions of a business are fixed in the short run, partial budgeting looks at changes in resources that are not fixed, often times looking at long-term structural changes to a business practice. Only items that change from one alternative to the next are considered in the calculations.

The partial budgeting example in Figure 1 illustrates some items that might be considered in evaluating the financial feasibility of transitioning to composting versus continuing to use a rendering service. In the left column, positive returns to the operation after the proposed change are totaled. These items include **Additional Returns** to the operation and **Reduced Costs.** If it is possible to sell compost, this might be an example of an additional return, while reduced rendering fees would be an example of reduced costs.

The right column of the partial budget totals negative returns to the operation after the proposed change. **Additional Costs** and **Reduced Returns** comprise these negative financial aspects of a proposed change. An example of additional costs is additional equipment, labor, and repairs specific to the composting operation.

After all items are accounted for in the partial budgeting process (Additional Returns, Reduced Costs, Additional Costs, and Reduced Returns), the negative column (B) is subtracted from the positive column (A) to show the final result of the partial budget. If the result of this calculation is positive, the proposed change is considered to be a financial benefit to the operation. In the above example, the result is a positive $400 ($1,250 - $850 = $400). This means that, assuming all items are accounted for, the operation would be $400 better off by switching to a composting operation.

Of course, the result of this calculation will vary depending on operation size, location and resources. The intent of

the partial budgeting process is to “clear the smoke” of all aspects of the operation that will not be changed under the proposed change. By only considering the items relevant to the proposed change, the true effects on an operation’s profitability are highlighted.

Partial Budget Form

Proposed Change	Composting Livestock Mortalities Vs. Rendering Service (10 Cows Annually)		
Additional Returns		Additional Costs	
Compost/Fertilizer		Equipment Repairs	150.00
		Carbon Source	200.00
		Equipment Labor	500.00
Total Additional Returns	$ -	Total Additional Costs	$ 850.00
Reduced Costs		Reduced Returns	
Rendering Charges	1,250.00		
10 @ $125			
Total Reduced Costs	$ 1,250.00	Total Reduced Returns	$ -
A. Total Additional Returns & Reduced Costs	$ 1,250.00	**B. Total Additional Costs & Reduced Returns**	$ 850.00
		Net Income Change (A Minus B)	$ 400.00

Figure 1. Example of a partial budget comparing composting and a rendering service.

Partial Budget Form

Proposed Change			
Additional Returns		Additional Costs	
Total Additional Returns	$ -	Total Additional Costs	$ -
Reduced Costs		Reduced Returns	
Total Reduced Costs	$ -	Total Reduced Returns	$ -
A. Total Additional Returns & Reduced Costs	$ -	**B. Total Additional Costs & Reduced Returns**	$ -
		Net Income Change (A Minus B)	$ -

Figure 2. Blank partial budget form.

State Regulations and Permitting

The following discussions are based on state level regulations at the time of publishing. Local county or city regulations need to be researched before beginning your compost operation because they can place additional constraints on a composting operation. Likewise, consult the regulatory agency directly, or an Extension specialist knowledgeable on the subject.

Montana

State Regulations

Montana Code Annotated (MCA) 75-10-213 regards dead animal disposal. Animal composting facilities are listed as approved disposition of dead animals; there is also reference to the required use of permitted composting facilities. However, in the exclusion that follows, it states that a person cannot be prohibited from disposing of waste generated in reasonable association with the person's agricultural operation upon land owned or leased, as long as no public nuisance or health hazard is created.

The Montana Department of Environmental Quality (MT-DEQ) reserves the right to revoke such privileges or exclusions if a proper plan for construction, operation, and maintenance of the composting facility is not followed, thereby resulting in a nuisance or public health hazard. Generally, the exclusion would not apply to divided land with tracts of land five acres or less in area. An alternate interpretation for permitted animal feeding operations (CAFOs with an MPDES Permit) is that mortality management practices defined and approved through that process would be authorized. In conclusion, properly designed and managed mortality composting can be done on property under the producer's legal control with said producer's animals without permit, unless a nuisance or health hazard is declared.

Permitting Considerations

The MT-DEQ Solid Waste Division issues permits for composting operations in the state. They have a two-tiered system differentiating between large composters, that require a Class II Solid Waste Management System Permit, and small composters, which require a Small Composter Facility License. However, on-site mortality composting with that producer's animals may be done without permit under the conditions referenced in State Regulations for Montana. Contact the Montana Department of Environmental Quality - Solid Waste Division at 406.444.5300 for more information.

Wyoming

Regulations

Regulations that would apply to mortality management with composting are tied to Wyoming's Department of Water Quality. Section 14 of the state's water quality guidance states that dead animals or solid waste shall not be placed or allowed to remain in Wyoming surface waters. Compost is generally considered to be part of the solid waste stream and as such must stay out of the state's surface waters.

Animal feeding operations have specific regulations that require the preservation of water quality. Animal feeding operations must be sized to contain precipitation and runoff from a 100-year, 24-hour storm. Any activity that would jeopardize water quality is not allowed. All Wyoming surface waters which have the natural water quality potential for use as an agricultural water supply shall be maintained at a quality which allows continued use of such waters for agricultural purposes. Unless otherwise demonstrated, all Wyoming surface waters have the natural water quality potential for use as an agricultural water supply.

Permitting

A permit to compost dead animals associated with a livestock operation is likely not needed. Those considering composting in Wyoming are encouraged to read Solid Waste Guideline #17 from the Wyoming Department of Environmental Quality and Wyoming Department of Agriculture. Questions should be directed to the WDEQ ((307) 777-7752).

Colorado

Regulations

In Colorado, there are two regulatory bodies involved in composting, the Colorado Department of Public Health and Environment (CDPHE) and the Colorado Department of Agriculture (CDA). The CDPHE's focus is on protecting public health and the environment at the composting site, while the CDA's focus is on protecting consumers from poor quality compost and guiding compost uses. The CDPHE regulations will be summarized in the Permitting Considerations section, and the CDA regulations will be described in the Compost Fate section.

Permitting Considerations

The CDPHE is responsible for the Solid Waste Regulations in Colorado as they apply to composting facilities (Section 14). There is, however, an agricultural exemption that is granted under certain conditions:

- The composting feedstocks are all agricultural wastes (from crop or animal production) generated onsite.
- The only feedstocks allowed to be imported onto the composting site from off-farm are wood chips and tree branches. They can only be brought on-farm in quantities necessary for effective composting, and they can only be stored for a maximum of nine months. In the case where off-farm feedstocks are brought on-farm for composting, the finished compost can only be applied to agriculturally zoned land.

Detailed information describing these requirements is found online in the regulation itself (www.cdphe.state.co.us/hm/sw/section14/basispurpose.pdf).

New Mexico

Regulations

In New Mexico, the primary regulatory body that addresses composting is the Solid Waste Bureau with the New Mexico Environment Department. Secondary authority is found in the Groundwater Quality Bureau for protection of water resources in, around, and below a composting site. Regulations are applicable based on tonnage per year. The regulations are summarized in the Permitting Considerations section.

Permitting Considerations

The New Mexico Administrative Code requires any person operating or proposing to operate a composting facility that accepts greater than 25 tons per day annual average compostable material or greater than five tons per day annual average of material that would otherwise become special waste (e.g., sludge, offal), shall submit a permit request and plans outlined in the administrative code. Much of the language is intended for those that intend to accept mortality or offal from outside sources. An individual that generates less than five tons per day of what would be considered special waste (i.e., offal, mortality, etc) would not be subject to regulation but should follow best management procedures and be especially mindful of nuisance ordinances and any county regulations. For more detail and information please visit the Title 20 website at www.nmcpr.state.nm.us/nmac/parts/title20/20.009.0003.htm

or the Solid Waste Bureau's website at www.nmenv.state.nm.us/swb/

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Quick Reference Guide

Critical components of livestock mortality composting. Refer to text for more complete explanations.

Step	Considerations
Planning	**Does it make sense for your operation?** Composting is a good alternative for any operation that has appropriate space and equipment for moving mortalities and compost materials. **Permitting:** Check with county and state agriculture and environmental offices (see section "State Regulations and Permitting" for more information). **Minimum tools:** tractor with frontend loader; 36- to 48-inch compost thermometer.
Select a site	**Size:** About 200 cubic feet per 1000 lbs. of livestock mortality, or 10 x 10 x 6 feet for a single large animal pile, or 6 x 6 x 6 feet for a bin. **Shape:** Windrows are best for airflow and ease of management, but bins made from wood or large hay bales allow tighter piling and a smaller footprint. **Location:** Choose an area with enough space to build and turn compost, deliver and move mortalities and base, core, and cover materials. It should be away and downwind from neighboring properties where scavenger activity can be monitored and discouraged. **Drainage:** Choose fine (not sandy or gravelly) well drained soils at least 3 feet above ground water and 300 feet from streams, ponds, wells, other water resources. An ideal site would have a gentle slope for drainage. Underlay piles on coarse soils with 6 inches of compacted sand or gravel, or sometimes clay or concrete. Construct berms to divert runoff if necessary. **Covering:** Compost piles in the semiarid west generally do not need to be covered, but should be monitored for runoff or seepage during unusually wet periods events.
Build the compost pile	**Lay the base:** 12 to 24 inches of wood chips or shreds that allow air flow and are not compactable or excessively wet. Spread to allow 18- to 24-inch margin. **Prepare the animals:** Breaking up large mortalities will speed the process. The body cavity should be opened and the rumen punctured for cattle, sheep, and goats to prevent excessive bloating and displacement of cover material. **Place the animals:** Place large mortalities on one side in the center of the base material. Smaller mortalities can be stacked with 8 to 12 inches of core material between layers. **Place the core:** 12 to 18 inches of fine, actively composting material with 50 to 60 % moisture content, such as manure, silage, or recycled compost is ideal *(squeeze test: at 50-60% moisture a few drops can be squeezed from a handful of material)*. Adding water is often necessary to start at this moisture level. **Place the cap:** 6 to 12 inches of fine, moist, low-odor material such as sawdust with 50 to 60 % moisture content to achieve 18- to 24-inch final margin around mortalities. Form flat or troughed top to collect moisture in dry regions. Peak the top to shed moisture in wetter areas.

Composting stage: 3 to 6 months	**Monitor temperature:** Thermophilic phase: Interior temperature should rise to 130-160^0 F within 2 weeks; if it doesn't, check moisture, start over. **Monitor cover:** Watch for odors, flies, and exposed mortalities from scavenger activity or movement by wind or water and cover with more material as needed. **Manage:** Turn the pile when temperature declines to <80^0 F for seven days. Check the moisture content right after turning and add water if necessary. If the temperature spikes again after turning, turn again when it declines.
Curing stage: 4 to 8 months	**Monitor temperature**: Mesophilic phase; warm, not hot temperatures. Bones breakdown during this stage in a slower decomposition process. The process is complete when the temperature stabilizes near ambient air temperatures. **Manage:** If temperature drops, the pile may need to be turned or mixed and moisture adjusted again. A small temperature increase after mixing indicates that the mesophilic curing process is underway.
Storage	Screen to remove remaining bones to reincorporate in to composting process. Store until land application or reuse in the core of a new compost stage.
Field application	Apply on the premises, or on fields where owner/manager is aware of the source of the material. Bone fragments can cause alarm if unexpected. Have the material tested for nutrient content and apply to non-food crop fields according to soil test based recommendations.

CATTLE RECEIVING STANDARD OPERATING PROCEDURES (SOP) FOR CONTROL OF NON-AMBULATORY DISABLED CATTLE AND AGE DETERMINATION OF CATTLE FOR SLAUGHTER

By: Ryan R. Baumert, HACCP Specialist, University of Nebraska-Lincoln
Dr. Dennis Burson, Meat Science Extension, University of Nebraska-Lincoln

2-17-04

This document is to be used as an example of an SOP for control SRMs in a slaughter operation, in accordance with USDA-FSIS Notices 4-04 and 5-04. Each operation should modify this document or create a new SOP according to the in-plant operations.

Non-Ambulatory Disabled Cattle

Non-Ambulatory is defined by 9 CFR 309.2(b) as:

> Livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions.

Procedures:

1. Cattle that meet the definition of Non-Ambulatory will no longer be accepted for slaughter at this establishment.
2. If an animal becomes Non-Ambulatory after it has passed ante-mortem inspection, slaughter personnel will notify inspection and verify that it was ambulatory at ante-mortem inspection, before beginning the slaughter process.
3. Cattle that are condemned during ante-mortem inspection will be properly disposed of in accordance with 9 CFR 309.13. Slaughter Manager will record the disposal process and maintain a file on-site.

Determination of Cattle Age and Identification for Control of SRMs

Procedure:

1. The age of the animal(s) will be determined for all animals thought or intended to be young beef (< 30 months of age). Slaughter operations will require documentation of the age of the live beef animal(s) at receiving. Records from a farm or ranch on which the animal(s) was born and finished, could include:
    - Animal identification (i.e. ear tags) with the corresponding calving date record
    - Calving Season Dates (beginning and ending dates)
    - Cow Artificial Insemination Date or Breeding Season Dates (beginning and ending dates)

    Records from feedlots could include:
    - Receiving/Processing Records of animals with identification of the producer/backgrounder. Producer/backgrounder records must identify the age of the animals.

- Animal Identification (i.e. ear tags) given at receiving with corresponding producer identification/calving records or certified group calving date range (beginning and ending dates)

2. Animal identification and age classification (< 30 or ≥30 months of age) will be recorded. The corresponding carcass identification will also be recorded.
3. In the absence of age documentation, the age of this animal(s) will be determined using the dental examination according to FSIS Notice 5-04.
    a. Cattle without age documentation could be managed as ≥ 30 months of age, if desired.
4. Animals thought or intended to be old beef (≥ 30 months of age) will not require age documentation.
5. If possible, animals ≥ 30 months of age will be held for slaughtering after animals < 30 months of age are slaughtered. If this is not possible a full clean-up and sanitization will be completed prior to continuing with animals under 30.

Monitoring:
Records at receiving will be collected by the Slaughter manager or designee

Corrective Actions:
1. If age documentation is not available at receiving, the producer/feedlot will be notified that the animal is being held for dental examination or being managed as ≥ 30 months of age.
2. If age documentation is not available at receiving, the driver and producer/feedlot will be notified in writing of the plant's age and animal identification procedures.

Verification:
1. The slaughter manager will review the records daily for completeness.
2. The slaughter manager will observe the receiving monitoring activities once every three months for proper procedures.
3. The plant management will review the SOP as new scientific or regulatory information is made available.

Records:
1. Cattle receiving log
    a. Animal ID and Age Documentation
    b. Verification

CATTLE ReceivinQ SOP |SRMs) LOG

Date	AnimaiiD	Carcass Lot#	Records		No Records		Monitor **(time/initials)**	Verification	
			< 3U Months	0::3U Months	< 3U Months	0::3U Months		Records* (time/initials)	Monitoring** (time/initials)

*Records Verification is performed once per day of receiving. -Monitoring Verification is performed once per month of receiving.

Consumer Health Services
2219 Carey Ave. ● Cheyenne, WY 82002
Phone: (307) 777-7211 ● Fax: (307) 777-6593
Web: agriculture.wy.gov

WYOMING DEPARTMENT OF AGRICULTURE
CONSUMER HEALTH SERVICE
2219 Carey Avenue
Cheyenne, WY 82002

CHEMICAL COMPOUND CHECK LIST

Plant: ______________________ Address: ______________________

Inspector: ______________________ Date: ______________________

Compound	Approved	Approved use of the compound

Wyoming Department of Agriculture
2219 Carey Ave. ● Cheyenne, WY 82002
Phone: (307) 777-7122 ● Fax: (307) 777-6593
Web: agriculture.wy.gov

The Wyoming Department of Agriculture is dedicated to the promotion and enhancement of Wyoming's agriculture, natural resources and quality of life.

Retail Meat Label Approval

Instructions: This form is to be completed by the meat plant owner or manager and reviewed by the Inspector in Charge. Retail labels approved on this form may be used for all pre-packaged meat products not displaying the Wyoming or federal mark of inspection. The retail meat label checklist must be completed by the Inspector in Charge and attached to this form for each label approval. Attach the label(s) to the reverse side of this form.

Product Name_____

Plant Name_____

Inspector_____

Product Formula: List all ingredients by weight or percentages, in descending order, including batch size. If this is repackaged from a bulk product, attach a copy of the ingredients label.

Method of Preparation: Describe how this product will be made.

Wyoming DEPARTMENT OF Agriculture

2219 Carey Ave. ● Cheyenne, WY 82002
Phone: (307) 777-7122 ● Fax: (307) 777-6593
Web: agriculture.wy.gov

The Wyoming Department of Agriculture is dedicated to the promotion and enhancement of Wyoming's agriculture, natural resources and quality of life.

Affix label(s) here:

Signature of owner or plant manager_____

Signature of Inspector in Charge_____

Date_____

Restricted Ingredient Log

Since nitrites and nitrates can be toxic to humans, the use of these ingredients in formulations is carefully controlled. The maximum level of these additives that is acceptable is spelled out in the FSIS regulations. The amount of nitrite added to product must be regulated at the formulation step, based on the total amount of meat and meat by-products. If a bulk cure is to be used, ensure the percentage of nitrates is known. The operator shall verify as part of the HACCP system that recipe and method of production will result in product compliant with the permitted level of use.

Date	Product Description	Batch Size (lbs)	Amount of cure (oz)	Lot size	Lot code	Signature

Wyoming DEPARTMENT OF Agriculture

CONSUMER HEALTH SERVICES PLAN REVIEW PACKET

All facilities must be inspected and licensed prior to operation. Submitting this form does not give permission to open or operate an establishment.

To ensure a timely review, the following documents shall be submitted to the department for approval at least 30 days prior to construction

1. Completed Plan Review Packet
2. One complete set of floor plans, drawn to scale, showing layout of equipment and mechanical systems. Refer to Ch. 2, Sec. 7 of the Wyoming Food Safety Rule or Ch. 2 of the Wyoming Pool Rule
3. Refer to specific plan review packet for additional requested information

Once the plan review packet has been approved, a pre-opening inspection shall be completed, license application completed and fees paid to Wyoming Department of Agriculture before a license will be issued. A license fee of $100.00 will be required at time of licensing. Please make checks payable to: **Wyoming Department of Agriculture Consumer Health Services Section.**

Area inspector contact information and entire written regulations can be found at http://wyagric.state.wy.us/divisions/chs, or by contacting the Consumer Health Services Division of the Wyoming Department of Agriculture at 307-777-7211.

Mark All That Apply:

___ New construction
___ Conversion of an existing building
___ Remodeling
___ Change of type of operation
___ Change of ownership
___ Requested by regulatory authority

_____
Applicant's printed name & title:

_____
Applicant's signature date of signature

Date Plan Review Submitted: _____ Anticipated Opening Date: _____

GENERAL INFORMATION

TYPE OF ESTABLISHMENT (CHECK ALL THAT APPLY)

☐ Aquatic Features	☐ Bulk Water	☐ Dairy	☐ Dietary Supplement	☐ Manufactured Food	☐ Meat Plant	☐ Mobile Unit or Push Cart	☐ Retail Food

Name of Establishment:	Phone:
Address:	Cell:
City:	Fax:
State/Zip:	Email:
County:	
Website:	

OWNERSHIP INFORMATION

Individual Name:	Phone:
Title:	Cell:
Corporate Name:	Fax::
Mailing Address:	
City:	Zip:
State:	Email:
Form of Organization:	Date formed and state where incorporated:
☐Individual ☐Association ☐Corporation ☐Partnership ☐Other entity:	

ON-SITE CONTACT INFORMATION (☐ CHECK IF SAME AS ABOVE)

Name of Primary Contact	Phone:
Address:	Cell:
City/State:	Zip:
Additional contact/title:	Phone:
Additional contact/title:	Phone:

DAYS AND HOUSE OF OPERATION

Days	☐ Sun	☐ Mon	☐ Tue	☐ Wed	☐ Thurs	☐ Fri	☐ Sat
Hours	to	to	to	to	to	to	to

Wyoming DEPARTMENT OF Agriculture

MONTHS OF OPERATIONS											
☐ Jan	☐ Feb	☐ Mar	☐ Apr	☐ May	☐ Jun	☐ Jul	☐ Aug	☐ Sept	☐ Oct	☐ Nov	☐ Dec
If a seasonal operation or irregular hours will occur, please explain:											

ADDITIONAL COMMENTS

FOR OFFICE USE ONLY
Date Plan Review Received: _____ _____ _____ _____ _____ _____
Plan Review Received by: _____
Date Plan was Reviewed: _____ _____ _____ _____ _____ _____
Approved: _____ **Denied:** _____
Comments:

MEAT SLAUGHTER FACILITY PLAN REVIEW WORKSHEET

I. Meat Slaughter Facilities

A. Will the slaughter facility have railing to transport carcasses? ☐Yes ☐ No
If yes, please complete Table 1 below. Please note, that to prevent contamination of carcasses, rails should be arranged to provide enough room for carcasses to move without touching equipment, walls, columns, other fixed parts of the building, and other carcasses.

Table 1: Railing		
Area	**Location**	**Rail Height (in feet)**
Kill Floor		
External Rail Height		
Drop Rail		
Other:		
Other:		

B. Will the slaughter facility have any hoists? ☐ Yes ☐ No
If yes, please complete Table 2.

Table 2: Hoist(s)		
Location	**Height**	**Capacity (in pounds)**

C. Describe cleaning and sanitizing procedures, location, and frequency for troll hooks and gamble hooks used for operations.

D. Floors, walls, and ceilings in slaughter areas, walk-in cooler/freezers, should be constructed so that they are rigid, durable, non-toxic, non-corrosive, and impervious to moisture, should be a light solid color, and should be smooth or textured with an easily cleanable open pattern. Please use the finish schedule in Table 3 below to indicate interior floors, walls and ceiling finishes for each area within the slaughter facility.

Table 3: Finish Schedule				
Room Name	**Floors**	**Coving**	**Walls**	**Ceilings**
Kill Floor (Example)	*Quarry Tile*	*Sealed Cement*	*Fiberglass Reinforced Plastic (FRP)*	*Paneling*

* Provide a specification sheet for all floor, walls, and ceiling materials.

II. Slaughter Equipment

A. Any commercial slaughter equipment that is intended for use in an inspected facility shall meet the requirements of the Wyoming Food Safety Rule, Chapter 4 and Chapter 6, 9 CFR 317.20-21 and CFR 416 – 416.6. Please use Table 4:Equipment Schedule to indicate equipment to be installed in facility .

Table 4:Equipment Schedule				
Equipment Installation List				
ID # on Plan	**Equipment**	**Make/Model**	**New (N) / Used (U)**	**Plumbing Required Y/N**

***Provide specification sheets for all equipment. For used equipment, provide a photograph.**

B. Will the slaughter facility have a knife sterilizer? ☐ Yes ☒ No
If yes, please complete Table 5: Knife/Saw Sterilizer Schedule below.

TABLE 5: KNIFE/SAW STERILIZER SCHEDULE						
NAME OF KNIFE OR SAW AND LOCATION	**KNIFE OR SAW DIMENSIONS (INCHES)**			**DIMENSIONS (INCHES) OF STERILIZER COMPARTMENT**		
	LENGTH	WIDTH	DEPTH	LENGTH	WIDTH	DEPTH

III. Slaughter Facility Processes

A. Describe the kill chute that will be used for each species. Kill chutes will be required to be tailored for the animal species that will be slaughtered.

B. Will the facility be using a head catch? ☐ Yes ☐ No

C. Describe the livestock pens that will be used with each species

i. Where will suspect pens be located?

ii. Where will carcass retain cage be located?

D. Describe how the facility will be separating carcasses over the age of 30 months from carcases younger than 30 months:

E. Describe how the facility will be identifying custom carcasses:

F. Describe how the facility will stun each animal species being slaughtered:

G. Describe the facility secondary means of stunning:

H. Describe how the facility will bleed each animal species being slaughtered:

I. If the facility is slaughtering hogs, will the hogs be skinned or scalded?

If scalded, please describe and provide a spec sheet for scalding vat:

Please describe and provide spec sheet for dehairing machine:

J. What equipment will be used to wash the head (i.e. rack or station)?

K. Describe how the facility will bung each animal species being slaughtered:

L. How will the facility be removing hides? (ie. Hide remover and type) Where will hides be stored?

M. Please describe your facilities plan for BSE/SRM removal at slaughter below (SOP required):

N. How will the facility determine age of animals?

O. What forms will the facility cool carcasses?

☐ Whole ☐ Quarter

☐ Half ☐ Other:

P. Where will the facility hold carcasses after slaughter?

Q. In Table 6:State Inspection Equipment Schedule please fill out to indicate the make/model of required equipment for state inspection.

Table 6:State Inspection Equipment Schedule		
Equipment Installation List		
ID # on Plan	**Equipment**	**Make/Model**
	Head Washing Station	
	Head Inspection Stand	
	Viscera Cart	
	Inspection Table	
	Other:	
	Other:	
	Other:	
	Other:	
	Other:	
	Other:	

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USDA/NCDA&CS FACILITY GUIDELINES FOR MEAT PROCESSING PLANTS

Appendix **A—Guidance on Establishment Facilities and Equipment**

OVERVIEW

This Guidebook is intended for use by meat and poultry establishments in considering decisions about design and construction of their facilities, as well as the selection of equipment to be used in their operations. The material that forms the basis for this Guidebook is drawn principally from technical knowledge and experiences used by the Food Safety and Inspection Service in making its prior approval decisions about the acceptability of facilities and equipment.

The Agency is no longer making these prior approval decisions for inspected establishments; however, the technical considerations on which those decisions were based may be of interest to establishments in the future. That is the material which is reflected in this Guidebook.

Chapter 1
LOCATION

Selecting the location for your establishment is an important factor in providing a sanitary environment for producing meat and poultry products. When selecting a location, you will need to consider the physical environment of the site, accessibility, separation of your premises from other businesses, common areas shared by you and other establishments, and whether or not you will conduct uninspected businesses such as retail stores or custom slaughter on or near your premises. This chapter provides guidelines you may wish to consider when the select a location for your establishment.

1. Site

The size of the site should allow for all buildings, parking lots, access roads, and future expansion. The site should be large enough to accommodate a potable water supply for your processing needs, and a sewage system that can efficiently handle liquid waste and process water created by your establishment. In addition, potential building locations should be evaluated for sanitation hazards. In determining that possibility, consider the following guidelines:

- To the extent possible, establishments should be located in areas free of industries that attract vermin such as sanitary landfills and junk yards.
- To the extent possible, establishments should be located in areas free of odors and airborne particulate matter that may be produced by neighboring industries or other outside sources, such as oil refineries, trash dumps, chemical plants, sewage disposal plants. dyeworks, and paper pulpmills.
- The prevailing winds are an important factor in site determination because substances emanating from more distant sources may be a problem if the winds carry them to the establishment site.

2. Separation of Official and Non-Official Establishments

Sometimes an establishment is located next to or in the same building as other businesses which are not under FSIS inspection. In those circumstances you should take great care to keep product from becoming contaminated from the operation of the adjoining business.

Chapter 2

LAYOUT

One of the most important decisions you make in building or modifying an establishment is how you plan the layout of your building, including the placement of rooms and equipment, product flow and people traffic patterns. Not only does a poorly designed establishment affect your productivity, but it may result in congested operations that can lead to unsanitary conditions. This chapter provides guidelines that you may wish to consider in planning any modifications to your existing establishment or in building a new one.

1. Flow of Operations

The direction in and means by which product moves or flows within a plant is an important but often neglected consideration that can have enormous influence on sanitation and the safety of finished products. From a product flow standpoint, all raw meat and poultry products ought to be considered as potentially microbiologically contaminated and handled accordingly. Product being processed should flow progressively from highest potential exposure to contamination to the least potential exposure to contamination, with intervening processes designed to remove or otherwise reduce the contaminants whenever possible. The flow of air and people should be just the opposite, moving from the cleanest areas progressively toward less clean areas.

When designing product flow, consider the following:

* Moving product from raw to final cooked product areas to systematically reduce the risks of contamination along the way.

* Locating trash dumpsters and receptacles so that they do not create a risk of product contamination.

* Selecting rooms large enough to permit the installation of all necessary equipment with space for establishment operations and inspection.

* Locating people passageways to provide maximum clearance to products, work areas, and production equipment.

* Keeping truckways unobstructed.

2. People Traffic Flow

Inadequate control of the flow of people through product operational areas is one of the most serious risks for production contamination. People can act as carriers and bring from the outside contaminants such as dirt, debris, and vermin which are ideal vectors for microbiological growth and which can both directly and indirectly contaminate product. Ways in which you can reduce and control the flow of people include the following:

* Establishment design should not require personnel not routinely assigned to specific work areas to be routed through those work areas. For example, personnel working in the live animal areas should not be required to travel through cooked product areas to use welfare rooms.

* Welfare rooms, such as toilet rooms, dressing (locker) rooms, and cafeterias, should be designed to minimize contamination because of the traffic patterns of the people.

3. Separation of Raw and Ready-to-Eat Product

Cross contamination of ready-to-eat product by raw products may occur if the layout does not provide for separation of these products. To prevent cross contamination in the preparation of products, the following are guidelines for you to consider:

* Exposed cooked product areas should be physically separated from other areas of the establishment. Non-pedestrian passage openings may be present for the transfer of product or supplies.

* A ventilation system should be used to direct air flow away from exposed cooked product areas.

* Environmental control equipment such as fans and evaporator condensation pans should not be located above the product.

* Welfare rooms, dry storage, maintenance, box/carton make up, packaging, and palletizing areas should be separate, but adjacent to, the exposed cooked product rooms.

* Cooked product should be covered in rigid containers to protect it from contamination while in storage.

* Separate coolers and/or freezers should be available to use for exposed cooked product.

* All cooking apparatuses for exposed products should have separate entry and exit portals.

* No cooked product wash or reconditioning sinks should be used.

4. Perishable Product Rooms

Special care should be taken in perishable product rooms to inhibit growth of microorganisms in operations which could contaminate product. In addition, care should be taken to prevent contamination from other operations such as where raw ingredients are prepared. Non-meat or non-poultry ingredients should be prepared in a room or rooms separate from meat or poultry processing rooms. For example, preparation of raw vegetables for use in product should be performed in a room separate from meat or poultry processing rooms.

5. Edible and Inedible Products Rooms and Areas

Edible product can be easily contaminated by contact with inedible products, grease or sewage from inedible product areas. In order to prevent this contamination from occurring, consider the following in the placement of these rooms:

* The flow of inedible and condemned product should be designed so that it does not come into contact with edible product.

* An inedible products department should be separate and distinct from the areas used for edible products. Inedible product rooms, grease interceptors, and sewage treatment equipment must be located away from edible product rooms.

* Hooded, closed chutes that lead directly from the slaughter room to the inedible handling room are designed to prevent objectionable odors from inedible and condemned products from entering edible products rooms.

* If rendering facilities are not available at the establishment watertight storage facilities should be provided to hold these products before their removal to rendering plant. These storage facilities should be separate and apart from edible products rooms, and constructed to prevent unsanitary conditions including attraction or harborage for vermin.

* Areas for inedible trucks should be paved and enclosed for ease of cleaning and to control odors and vermin.

* Where necessary, the boiler room should be a separate room to prevent dirt and objectionable odors entering from it into rooms where meat products are processed or handled.

6. Byproducts for Use in Animal, Pet, or Fish Food

Establishments that process byproducts into animal, pet, or fish food should provide rooms for decharacterizing, chilling, packaging, or

otherwise preparing the byproducts. Consider the following guidelines when designing and constructing these rooms:

* Byproducts to be used as animal, pet, or fish food should be stored separately to prevent cross contamination and commingling with edible products.

7. Coolers and Freezers

Coolers and freezers need to have enough space to refrigerate and store product. Product should be stored in a manner that will preclude conditions which may lead to contamination of product. The following guidelines will assist you in preventing conditions which could lead to contamination of your product:

* Coolers and freezers, including doors, should be constructed of materials that can be readily and thoroughly cleaned, and durable, rigid, impervious to moisture, non-toxic, and non-corrosive. Freezer doors should be constructed and installed to prevent accumulation of frost.

* Coolers and freezers should be equipped with floor racks, pallets or other means to ensure protection of product from contamination from the floor.

8. Dry Storage

Packaging materials and ingredients should be stored to preclude conditions which may lead to contamination of product. The following are guidelines which may assist you in the planning of your dry storage area:

* Dry storage materials should be stored in a room dedicated to dry storage only.

* The dry storage area should be constructed so that racks can be spaced away from the walls and passageways maintained between rows. This facilitates cleaning of the area. In addition, the construction should allow for all meat or poultry ingredients and/or packaging materials to be stored in closed containers on racks or pallets.

9. Incubation Room for Canned Products

A room or incubator for incubating samples of fully-processed canned meat or poultry must be provided in all establishments conducting regular canning operations. Consider the following guidelines when building this room:

* An accurate time/temperature recorder must be provided. To prevent temperature variations, a means for air circulation should be provided.

* Shelves should be provided to hold canned product. The shelves should be made of expanded metal or heavy gauge wire mesh and be removable for cleaning.

* The floor in the room should be pitched to a floor drain equipped with a removable screw-plug.

* The door of the room should be equipped for sealing by the inspector, if necessary.

10. Vehicular Areas Outside the Building

Special care should be given in the design of vehicular areas outside your building, not only to provide room for trucks and other vehicles to operate without damaging your building, but to prevent unsanitary conditions which might contaminate product in your establishment. You should consider the following in designing your vehicular areas:

* Areas outside the building where vehicles are loaded or unloaded should be paved with concrete or a similar hard surface. Hard surface areas allow these areas to be kept clean and eliminate the potential for water puddles or dust.

* Areas outside the building where vehicles are loaded or unloaded should be drained. Drainage from the loading docks should be confined to the immediate area of the dock.

* The vehicular areas should be large enough to accommodate the turning radius of the largest trucks or shipping vehicles used by the establishment.

* The vehicular areas adjacent to the establishment should have hose connections for cleaning.

Chapter 3

WELFARE FACILITIES FOR ESTABLISHMENT EMPLOYEES

One source of potential contamination of product is cross contamination from employee welfare facilities. In designing and locating employee facilities, great care should be given to preventing overcrowding and congestion and to providing enough handwash sinks and toilets for your employees. This chapter provides additional guidelines that you may wish to consider in making any modifications to or building any welfare facilities for your employees.

1. Dressing (Locker) Rooms

Dressing rooms must be provided for employees. In addition to privacy considerations, these dressing rooms should be located where they will not be a potential source of cross contamination of product. Consider the following guidelines for these dressing rooms:

* Dressing rooms should be separate from rooms or compartments where product is prepared, stored, or handled.

* Dressing rooms should be separated from the toilet area.

* Separate dressing rooms should be provided for each sex if both sexes are employed by the establishment.

* Dressing rooms should have abundant, well-distributed light of good quality.

* Separate dressing rooms for raw product and other product department employees will help prevent cross contamination of product.

* Receptacles for soiled clothing should be provided adjacent to employees' dressing rooms.

2. Lockers

Lockers should be provided for employees clothing and personal items. To prevent insanitary conditions, consider the following guidelines when choosing the type of lockers and the arrangement and locations for them:

* To prevent the potential for cross contamination, the location of lockers should be separate from rooms or compartments where product is prepared, stored, or handled.

* Lockers should be large enough to store a change of clothing and other personal items.

* For ease of cleaning, lockers should be constructed of materials that are rigid, durable, non-corrosive, easily cleaned and inspected, impervious to moisture, a light, solid color, with a smooth or easily cleaned texture, and have sloping tops.

* Lockers should either be installed so that there is enough room under them that they can be easily cleaned and inspected, or they should be sealed to the floor.

3. Drinking Fountains

Sanitary drinking water fountains should be provided. Consider the following guidelines when installing drinking water fountains:

* Drinking water fountains should be provided at convenient locations throughout the establishment to minimize the distance that employees need to travel to reach a fountain. This is especially important in preventing cross-contamination from employees working in raw or inedible areas and traveling to processing or ready-to-eat areas to use a fountain. Consider the following locations for placing drinking fountains:

** welfare areas including cafeterias, dressing (locker) rooms, and toilet rooms

** inspectors' offices

** edible product areas including kill floor, deboning, and cut-up areas

** inedible product areas

** immediately outside freezers and coolers

** storage areas

* Drinking water fountains should be connected to the potable water supply and either directly connected to the underfloor drainage system or should discharge through an air gap to a hub drain.

* Drinking water fountains should be other than hand operated, and if placed as part of handwash sink, should be located high enough to avoid splash from the sink.

4. Toilet Rooms

Toilet rooms can easily become a source of potential contamination of product. Care should be taken in the design of these rooms from their location in the establishment's layout to the number of toilets provided. Consider the following guidelines:

* Toilet rooms need to be separated from the rooms and compartments in which products are prepared, stored, or handled.

* Toilet rooms that open directly into rooms where meat products are exposed should have self-closing doors and should be ventilated to the outside of the building.

* Toilet rooms should be arranged so they are entered through an intervening dressing room or vestibule and not directly from a production or storage room.

5. Eating Rooms and Areas

To prevent employees from contaminating products or contaminating their food with microorganisms from the raw products or from their working environment consider the following:

* Separate eating rooms or areas should be provided for employees.

6. Handwash Sinks

One of the most important steps you can take to prevent cross contamination of product by your employees is to provide conveniently located handwash sinks. Handwash sinks are needed in toilet rooms, dressing (locker) rooms, and production rooms. Consider the following guidelines when making decisions as to where you need a handwash sink:

* Handwash sinks are needed near toilet rooms and dressing (locker) rooms. They should be other than hand operated. There should be hot and cold running water, soap, and towels. Single use towels should be used.

* Handwash sinks in welfare rooms and areas should have a combination mixing faucet delivering both hot and cold water with an high enough above the rim of the bowl to enable the washing of arms as well as hands.

7. Ventilation

In designing your welfare rooms, such as toilet and dressing rooms, care should be taken to make sure that they are ventilated to prevent odors from entering production areas. Consider the following guidelines:

* Welfare rooms that are not air conditioned should be mechanically ventilated through an exhaust fan taking air to the outside. Airflow from welfare rooms should be released outside the establishment.

* Toilet and dressing rooms that are located where no natural ventilation is available should be equipped with an exhaust fan (activated by a common switch with the lighting in the area) and a duct leading to the outside. Doors to dressing and toilet rooms ventilated in this manner should have a louvered section about 12 inches by 12 inches minimum in the lower panel to facilitate airflow.

8. Employees Working in Inedible Product Areas

Association of employees working in inedible product areas with other employees through common welfare rooms increases the risk of cross-contamination of product. To minimize this risk to product, consider the following guidelines:

* Separate welfare rooms for employees working in areas such as hide cellars, condemned or inedible product rooms, or live animal holding areas, from welfare rooms of other employees working with raw or heat processed, exposed, edible product.

Chapter 4

CONSTRUCTION

A frequently overlooked area of construction design is the selection of appropriate construction materials for the establishment. This chapter provides guidelines for construction and the selection of construction materials that you may wish to consider when making modifications to your current establishment or building a new one.

1. Building Construction Materials for Rooms (Finished Surfaces)

Production and storage areas need to be constructed with materials that are readily and thoroughly cleaned. Product in production and storage areas is at risk for contamination from indirect contact with materials used for construction of the building. In order to be readily and thoroughly cleaned, building construction materials in production and storage areas must be:

* Rigid and durable.

* Non-toxic and non-corrosive.

* Impervious to moisture.

* A light, solid color such as white.

* Smooth or textured with an easily cleaned, open pattern, for example, a pattern where the veins and depressed areas are continuous or have an outlet and are not enclosed.

In addition, consider the following guidelines for selecting construction materials:

* In non-production and non-storage areas, building construction materials should be easy to clean thoroughly.

* Special consideration should be given before using wood as a construction material.

** Wood is absorbent and can absorb not only water but other substances including chemicals that create a risk for contamination of meat or poultry products.

** Wood is easily damaged and may create wood particles (splinters) that contaminate meat or poultry products.

** If wood is used as a construction material in exposed product areas of the official establishment, it is recommended that the wood be milled smooth and completely sealed with a coating to prevent the wood from adulterating meat or poultry product. The coating should be able to be readily and thoroughly cleaned durable, rigid, impervious to moisture, non-toxic, and non-corrosive.

** The use of hot linseed oil to treat or coat wood in exposed product areas is not recommended because it promotes the growth of molds and fungi.

2. Floors

In addition to any obvious debris on a floor, product can become contaminated by the flooring or microorganisms living in debris in tiny crevices in the floor. In order to avoid these sources of contamination, consider the following guidelines when selecting and installing flooring in your establishment:

* Floors in areas where product is handled or stored should be constructed of durable, easily cleanable materials, and be impervious to moisture. Commonly used materials are concrete, quarry tile, brick, and synthetic material.

* Floors should be installed and maintained to reduce the likelihood of cracks, depressions, or other low areas that would accumulate moisture.

* Floors where operations are conducted should have a slip-resistant surface. Good results are obtained by using brick or concrete floors with abrasive particles embedded in the surface. Concrete floors should have a rough finish.

* Floors should be sloped to avoid puddles or depressions within the slope where water will stand.

3. Coving/Curbs

Coving is used at the wall-floor juncture, column (post)—floor juncture, and equipment support-floor juncture to provide a smooth transition for ease of cleaning and inspection. Consider the following guidelines when using coving or curbs:

* Coving in production and storage areas should include the following criteria:

** All seams should be tight-fitting and sealed to eliminate all cracks and crevices which may shelter insects, vermin, and microorganisms.

** The coving should eliminate any sharp angles that allow the accumulation of materials.

* Curbs should be provided to protect walls and wall finishes. Curbs should be high enough to protect the walls from pallets, trucks, or containers used in the establishment. Coving should be provided at the base of the curb.

4. Stairs

In selecting stairs consider the following:

* Stairs should have solid treads and closed risers and should have side curbs of similar material.

5. Catwalks and Access Platforms

When installing catwalks and access platforms consider the following guidelines:

* Catwalks and access platforms in edible product handling departments should be constructed of materials that meet the same guidelines as flooring.

* Open grating should not be used for the flooring of catwalks and access platforms inside the establishment, particularly in production areas. Dirt and other debris from shoe soles can be scraped off by the grating and contaminate product, packaging material, and equipment.

* Catwalks and access platforms should not be installed over production lines and processing equipment.

6. Interior Walls Including Posts and Partitions

To prevent product from becoming contaminated by contact with interior walls, care needs to be taken in selection of materials for the finished surface of walls. Consider the following when selecting a finish:

* Interior walls, in areas where product is stored or handled, should be finished with materials that will make them susceptible to being readily and thoroughly cleaned and impervious to moisture. Examples of such materials are glazed brick, glazed tile, smooth concrete, and fiberglass reinforced plastic (FRP).

* Walls should have a smooth texture, not one that is rough or uneven.

* Fasteners for wall covering material should be solid, smooth headed, and not have recesses which allows the collection of foreign material.

7. Ceilings

Ceilings, in areas where product is stored or handled, should be constructed to prevent the collection of dirt or dust that might sift through from the areas above or fall from overhead collecting surfaces onto equipment or exposed products. Therefore, it is recommended that ceilings and overhead structures be maintained free of sealing paint or plaster, dust, condensate, leaks, and other materials or defects. In addition, ceilings in areas where product is stored or handled should be constructed and finished with materials that can be thoroughly cleaned and are moisture resistant. Examples of such materials are smooth concrete and fiberglass reinforced plastic.

8. Windows and Skylights

Windows (and skylights) can be a potential source of contamination of product by dirt, water, debris, or broken glass. Consider the following when selecting and installing windows:

* All outside windows, except for those in receiving and feed rooms, should have protection to exclude insects, birds, and other vermin.

* Window ledges should be sloped about 45 degrees to prevent the accumulation of dirt, water, or debris.

* To avoid damage to window glass from impact of hand trucks and similar equipment, the sills should be at least 3 feet above the floor.

* Windows that are installed in walls in exposed product rooms should have panes of acrylic or polycarbonate plastic or other shatter-proof material.

9. Doorways and Doors (General)

Doors are barriers that allow the movement of product and people, but also present a barrier to contamination such as dirt, insects, and other vermin as well as the microbiological hazards that they carry. The door type, construction material, and room in which the door is located are all important considerations when doors are installed in the establishment. Doors are important in maintaining sanitary conditions especially in production and storage areas. In production and storage consider the following guidelines for doors:

The most effective doors have the following characteristics:

* They are impervious to moisture.

* They are tight fitting to minimize air exchange and to prevent the entry of insects and vermin into the establishments.

* They are self-closing and used throughout the establishment, especially in areas where toilet rooms open directly into rooms where meat and poultry are exposed, to prevent contamination of products with odors and their associated contaminants.

* They are high and wide enough to allow the movement of exposed product through the doorways without it coming into contact with the door or jamb.

* They are rigid and durable, and the junctions at jambs, walls, and floors are sealed to eliminate all cracks and crevices for debris, insects, and dirt to collect.

* Doors that open directly to the outside of the building from production rooms should have an intervening closed space, such as a vestibule or enclosed lock, to prevent the direct access of contaminants and microbial organisms to areas inside the establishment.

10. Types of Doors

In selecting a type of door for your establishment you need to consider the location of the door and whether or not product will be traveling through it. The following guidelines for different types of doors may be useful to you when selecting a door:

* The horizontal double-swinging, impact door is a bi-parting, inflexible panel door with plastic windows (vision panels) that swings only in the horizontal plane. If you select this door, consider the following:

** This door may be useful in rooms with dimensions that would not permit the use of a roll-up, vertical sliding or horizontal sliding door.

** Because this door must be manually opened, the door can be damaged creating sanitation and maintenance problems.

* The horizontal sliding door (manual and automatic) is a single or bi-parting, inflexible door that moves only in the horizontal plane. If you select this door, consider the following:

** This door may be useful in rooms with dimensions that would not permit the use of a roll-up or vertical sliding door.

** The automatic opening option is recommended not only for sanitation reasons, but it also prevents damage.

* The vertical sliding door (manual or automatic) is a single, inflexible panel door that moves only in the

vertical plane. If you select this door, consider the following:

** This door may be useful in rooms with dimensions that would not permit the use of a roll-up or horizontal sliding door.

** The automatic opening option is recommended not only for sanitation reasons, but it also prevents damage.

* The overhead garage-type door (manual or automatic) is a hinged, multi-paneled door that moves from the vertical to the horizontal plane. If you select this door, consider the following:

** This door may be an excellent choice for sheds or buildings used to store equipment, such as a lawn mower, that is used for the outside maintenance of the establishment's property.

** It is recommended that these types of doors not be used in exposed product areas or areas subject to wet clean-up because these doors have spaces between the panels that allow the collection of product, such as meat and fat, as well as contaminants.

* The roll-up door (manual or automatic) is a single flexible panel door that moves only in the vertical plane and when open, coils tightly onto a drum assembly. If you select this door, consider the following:

** This door can be an excellent alternative especially where space for opening a door is limited.

** Several additional features should be installed on this type of door to make it an effective barrier against contamination.

* The air curtain or air door is a door that uses a layer of air generated by mechanical fans to separate two rooms or areas. If you select this door, consider the following:

** This door needs to be carefully selected, installed, and maintained to be effective.

** If an air imbalance (pressure imbalance) develops at the door opening, the separation effect may be diminished or eliminated. Air imbalance can occur from air flow changes from any other openings in the rooms especially other doors.

** The movement of the air can stir up contaminants, such as dirt and dust, if the area around the door is not kept clean.

Chapter 5

LIGHTING, VENTILATION, REFRIGERATION, AND EQUIPMENT

Controlling the manufacturing environment is important in maintaining a sanitary environment in meat and poultry operations. This chapter provides guidelines concerning lighting, ventilation, refrigeration, and equipment for meat and poultry establishments that you should consider in building or modifying an establishment.

1. Lighting

Well-distributed, good-quality artificial lighting is needed at all places where natural light is unavailable or insufficient. Lighting is critical to maintaining a sanitary environment for slaughter and processing operations. Without adequate lighting, insanitary conditions are often difficult to see and correct. When selecting and installing lighting systems, consider the following requirements:

* Light fixtures in rooms where exposed meat or poultry is handled should ensure maximum safety, to preclude contamination of products with broken glass and prevent the collection of dirt, product, and debris on lamp surfaces, including fixture surfaces not easily cleaned or inspected.

* Lighting must be intense enough to allow both the establishment and inspection personnel to see insanitary conditions and product contamination. The intensity of lighting is measured in foot candles. The following charts provide recommendations for minimum foot candles for artificial lighting:

TABLE 1.—GUIDELINES FOR MINIMUM LIGHTING INTENSITY IN MEAT ESTABLISHMENTS

Area	30 ft. candles	50 ft. candles
General lighting (in areas where animals are killed, eviscerated, and products are processed or packaged)	X	
Offal cooler	X	
Carcass coolers	X	
Freezers	X	
Dry storage	X	
Ante-mortem inspection	X	
Suspect pen inspection area		X
Inspection stations		X
Establishment quality control inspection areas		X
Reconditioning and reinspection areas		X
All other areas	X	

TABLE 2.—GUIDELINES FOR MINIMUM LIGHTING INTENSITY IN POULTRY ESTABLISHMENTS

Area	30 ft. candles	50 ft. candles	200 ft. candles
Ante-mortem inspection	X		

TABLE 2.—GUIDELINES FOR MINIMUM LIGHTING INTENSITY IN POULTRY ESTABLISHMENTS—Continued

Area	30 ft. candles	50 ft. candles	200 ft. candles
Inspection station (traditional)		X	
Inspection station (NELS/SIS/NTI)			X
Pre and post chill inspection areas			X
Reconditioning and reinspection areas			X
Establishment quality control inspection areas			X
All other areas	X		

2. Ventilation

There should be enough ventilation for all areas of the establishment including workrooms, processing, packaging, and welfare rooms to ensure sanitary conditions. A good ventilation system is important to the production of wholesome meat and poultry products. Without controlling the quality of the air coming into the establishment, products may become contaminated with dust, insects, odors, or condensation. When designing your ventilation systems, you should consider the following guidelines:

* The ventilation system should be designed so that turbulence is avoided. The longer the distance the air has to flow, the greater the resistance the air encounters not only from static air, but from solid objects such as walls, equipment, people, and product.

* The ventilation system should be designed with the size of the establishment in mind. The larger the facility, the greater the volume of air that must be moved.

* The ventilation system should be designed to compensate for changes in outside temperature and humidity that cause condensation problems within the establishment.

* Screens and filters should be used where needed to screen out dust, odors, and insects brought in from the outside to prevent product contamination.

* Mechanical ventilation should be used to bring in fresh air to areas where natural ventilation is inadequate.

* Ventilation should prevent vapor formation, such as steam or fog, that would affect sanitation or interfere with the inspector's ability to perform inspection.

* When exhaust fans are installed, provision should be made to provide enough outside make up air to prevent air from being drawn into and through docks, coolers, and production areas to the area served by the exhaust fan.

3. Equipment (General Design and Construction)

Equipment materials should comply with 21 CFR, Parts 170–190 of the Food and Drug Administration (FDA) regulations for direct food contact.

Equipment and utensils used for handling as preparing edible product or ingredient in any official establishment should be easily cleaned and not be a source of contamination. Consider the following guidelines when selecting equipment.

* All direct product contact surfaces should be smooth; maintained free of pits, cracks, crevices and scale; corrosion and abrasion resistant; non-absorbent; shatterproof; nontoxic; and not capable of migrating into food products.

* Equipment should not be painted on areas in or above the direct product contact area.

* Construction materials that are sources of contamination include cadmium, antimony or lead as plating or the plated base material, lead exceeding 5 percent in an alloy and enamelware and porcelain used for handling and processing product.

* Equipment should be designed and installed in such a way that foreign materials, such as lubricants, heat exchanger media, condensate, cleaning solutions, sanitizers and other nonfood materials, do not contaminate food products.

* Equipment is self-draining or designed to be evacuated of water.

* All product contact surfaces allow contact with cleaning solutions and rinse water.

* Clean-in-place (CIP) systems should have sanitation procedures that are as complete and effective as those for cleaning and sanitizing disassembled equipment. To remove all organic and inorganic residues, CIP systems should meet the following criteria:

** Cleaning and sanitizing solutions and rinse water should contact all interior surfaces of the system.

** The system should be self-draining, with no low or sagging areas.

** The pipe interiors should be highly polished (120–180 grit) stainless steel for easy inspection.

** Easily removable elbows with quick-disconnect mechanisms should be installed at each change of direction. Elbows should be short enough to permit verification that the interior has been cleaned.

Chapter 6

WATER SUPPLY

The water supply should be ample, clean, and potable with adequate pressure and facilities for its distribution in the establishment and its protection against contamination and pollution.

1. Potable Water

An adequate supply of fresh clean water is of primary importance in plant operations. The first requirement is that the water supply to the plant be potable or safe for human consumption or food processing. The plant water supply must meet the potability standards in the National Primary Drinking Water Regulations issued by the Environmental Protection Agency (EPA).

2. Backflow

Public health officials have long been concerned about cross-connections that may permit backflow in potable water supply distribution systems. Cross-connections may appear in many forms and in unsuspected places. Reversal of pressure and flow in the water system may be unpredictable. Plumbing cross-connections between a potable and nonpotable water supply may constitute a serious public health hazard. There are numerous cases where cross-connections have been responsible for contamination of potable water and have resulted in the spread of disease. These concerns, as they relate to meat and poultry plants, deserve special attention. The problem is continual as potable water and piping systems are installed, repaired, replaced, or extended.

Two basic types of hazard may be created in piping systems: the solid pipe with valved connections and the submerged inlet. The solid pipe connection is often installed to supply an auxiliary piping system from the potable source. It is a direct connection of one pipe to another pipe or receptacle. Solid pipe connections may be made accidentally to waste disposal lines when it is incorrectly assumed that the flow will always be in one direction. An example would be connecting a line carrying used, nonpotable cooking water from a water jacket or condenser directly to a waste line without an air gap (see below). ''Backflow'' will occur with a submerged inlet if the pressure differential is reversed without an air gap. Submerged inlets are created when the outflow end of a potable water line is covered with water or other liquid. The other liquid may not be potable. Submerged inlets could be created by a hose lying in a pool or puddle of water on the floor.

Once a cross-connection exists, any situation that causes a pressure differential with the potable line having the lower pressure can result in contamination of the entire water distribution system and potable water supply. This is called backflow and can be produced under a variety of circumstances as illustrated below:

* Backsiphonage is one form of backflow. It is caused by negative pressure in the delivery pipes of a potable water supply and results in fluid flow in the reverse direction. It may also be caused by atmospheric pressure exerted on a pollutant liquid source that forces the pollutant into a potable water supply system that is under vacuum. The action in this case is the common siphon phenomenon. The negative pressure differential that will begin the siphoning action is a potential occurrence in any supply line.

* Differential pressure backflow refers to a reversed flow because of backpressure other than siphonic action. Any interconnected fluid systems in which the pressure in one exceeds the pressure of the other may cause flow from one to the other because of the differential. This type of backflow is of concern in buildings where two or more piping systems are maintained. The potable water supply is usually under pressure from the city water main. Occasionally, a booster pump is used. The auxiliary system often is pressurized by a centrifugal pump, although backpressure may be caused by gas or steam pressure from a boiler. A reversal in differential pressure may occur when pressure in the potable system drops below that in the system to which the potable water is connected. The best method of preventing this type of backflow is the complete separation of the two systems and/or an air gap. Other safety methods involve the installation of mechanical backflow prevention devices. All methods require regular scheduled inspection and maintenance to ensure ongoing effectiveness of installed devices.

Some areas that you should consider providing some form of protection from backflow and back siphonage include the following:

* Water supply to pens for wash down or livestock watering.

* Water supply to compressor cooling systems, cooling towers, and boiler rooms.

* Water supply to cleanup systems, clean in place (CIP) systems, etc.

* Water supply to hose connections.

Various mechanical antibackflow devices are available to prevent backflow into a potable water supply system. Generally, the selection of the type and number of fail-safe devices should be based upon the degree of hazard from contamination. Additional considerations include piping size, location, and the need to test periodically the backflow devices to ensure proper operation.

There are six basic types of devices that can be used to correct cross-connections:

* Air gap
* Barometric loops
* Vacuum breakers—both atmospheric and pressure type
* Double check valves with intermediate atmosphere vent
* Double check valve assemblies
* Reduced pressure principal backflow preventers
* Specific requirements concerning backflow can be found in local building and board of health codes.

Chapter 7

GENERAL PLUMBING FACILITIES

One of the most important factors to consider in the design and modification of establishments is the plumbing system. If the plumbing system is not properly installed, contamination of products can occur from flooding, back siphonage, stoppages and cross-connections with the potable water system. This chapter provides guidelines concerning the plumbing facilities, in meat and poultry establishments. For additional information on the design and modification of plumbing facilities, consult the National Plumbing Code.

1. Hose Connections and Hoses

There should be enough conveniently located hose connections with steam and water mixing valves or hot water connections provided throughout the establishment for cleaning purposes. Hose connections are important in promoting routine cleaning of the establishment. Consider the following guidelines when determining how many hose connections, location of hose connections, and storage of hoses:

* The number of hose connections depends on the number of drains.
* If a shut-off nozzle is provided on the hose after the hot and cold water mixing valve, the vacuum breaker at the hose connection to the mixing valve will not work. Vacuum breakers should be installed on the hot and cold water supplies prior to the mixing valve to prevent such problems.
* Hose connections should be provided with vacuum breakers to prevent back siphonage.

2. Establishment Drainage System

There need to be efficient drainage and plumbing systems for the prompt removal of liquid and suspended solid wastes from the processing environment. Consider the following guidelines when designing or modifying your drainage system:

* All plumbing should be sized, installed and maintained in accordance with applicable state and local plumbing codes, ordinances, and regulations.
* Drainage lines should be located so that if leakage occurs, it will not affect product or equipment.

3. Floor Drains

All parts of floors where operations are conducted should be well drained. There are two basic types of drains: point drains and trench drains. Point drains, the most commonly used drain in most areas, are located in strategic points in the room with the floor sloped toward the drain. The waste water flows over the surface of the floor until it reaches and is carried away by the drain. Trench drains involve a trough or trench that collects the waste from a larger area and directs the flow to a drain opening. The flooring is sloped toward the trench.

In a typical plant, one four-inch (10.16 cm) drainage inlet is provided for each 400 square feet (37.16 square meters) of floor space. A slope of about one-quarter inch per foot (2.08 cm per meter) to drainage inlets is generally adequate to ensure proper flow with no puddling. In dry production areas, where only a limited amount of water is discharged on to the floor, an adequate slope may be about one-eighth inch per foot (1.04 cm per meter). It is important that floors slope uniformly to drains with no low spots to collect liquid.

* The location of floor drains depends upon many factors such as the type of task conducted in the space, the geometric shape of the area drained, truck traffic patterns, and equipment locations.
* There are special drainage considerations in areas where there is a high volume of water usage. The water in trench drains should flow in the opposite direction of the product flow, for example, from the poultry evisceration to the picking areas.
* All parts of floors where wet operations or where floors are to be frequently hosed down should be pitched to floor or trench drains.
* Floor drains should not be located under equipment because it makes them inaccessible cleaning.
* Rooms without floor drains such as dry storage, large finished product coolers, and distribution warehouses may prefer to use mechanical cleaning machines instead of installing drains. Examples of such cleaning devices are floor scrubbers and dry/wet vacuum machines.

4. Trap Seals

Each floor drain should be equipped with a deep seal trap and vented properly to the outside. The purpose of such traps is to seal off the drainage system so that foul odors (sewer gases) cannot enter the plant. Effectiveness of the trap depends upon enough water remaining to constitute a seal. As water flows through the trap and down the drainpipe, suction is created that will pull the water out of the trap and break the seal unless the suction is broken by venting the drainpipe on the effluent side of the trap to the outside air. The seal can also be broken by evaporation of trapped water. This is not a problem in frequently used drains, but does occur where drains are seldom used.

5. Drainage Lines

All drainage lines must comply with local code requirements. They should be installed and maintained to be leakproof. To prevent drainage lines from becoming entrances into the plant for pests, including rats and mice, all lines must be equipped with effective rodent screens. Secure drain covers, in addition to keeping out pests, also serve to prevent blockage of the traps and drainage lines with product scraps or other material too large to flow freely.

6. Cleanouts

Cleanouts should be installed in the drainage system to prevent sewer blockages. Consider the following guidelines when installing cleanouts:

* Cleanouts should be located so they are readily accessible, and can be used without constituting a threat of contamination to edible products.
* To help avoid water puddling, cleanouts should be located on the ''high lines'' of floor slopes and away from traffic patterns.

Chapter 8

ESTABLISHMENT SEWAGE TREATMENT

The design and construction of sewage treatment facilities must comply with local code requirements. An improperly designed sewage system can contaminate the ground and water supply. This chapter provides

guidelines concerning sewage treatment at meat and poultry establishments that you may wish to consider in the installation of a sewage treatment facility.

1. Establishment Sewage Treatment

Sewage, one the most dangerous sources of human pathogens, should never be allowed to come into contact with products, equipment, utensils, or any food contact surfaces. When installing an establishment sewage treatment facility, consider the following guidelines:

* The system should be large enough to handle the amount of sewage that the establishment produces and accommodate future increases.
* If a private septic tank, pre-treatment, or treatment system is used, it should be designed and operated to prevent contamination of products.
* The sewage facility should be located away from product operations and ingredient and packaging storage areas.
* An area for cleaning solid waste containers with hot water, drains, and curbing should be located near any solid waste disposal facility.

2. Grease Catch Basins or Interceptors

Grease catch basins can be a source of contamination of products if not properly designed and located. Consider the following guidelines when constructing a grease catch basin:

* Catch basins or interceptors for recovering grease should not be located in or near edible product departments or areas where edible products are shipped or received.
* When a catch basin is located inside an establishment, it should be sealed with a gastite cover and located in a ventilated room.
* Grease catch basins should be constructed so they can be completely emptied of their contents for cleaning.
* The area surrounding an outside catch basin should be paved with impervious material, such as concrete, and drained.

Chapter 9

MEAT SLAUGHTER ESTABLISHMENTS

Although the flesh of healthy livestock is practically sterile, when the animal is killed many factors can contribute to contamination of the carcass including improperly designed and constructed slaughter facilities. This chapter provides guidelines for meat slaughter facilities to consider in building or modifying slaughter facilities.

Because different species of livestock need different slaughter facilities, this chapter is organized in the following way:

* Sections 1 through 8 describe general guidelines for facilities that slaughter cattle, calves, sheep, goats, hogs, and equines.
* Sections 9 through 37 describe additional guidelines for slaughter facilities as follows:
* Sections 9 through 19 contain additional guidelines for cattle slaughter operations;
* Section 20 contains additional guidelines for calf, sheep, and goat slaughter operations;
* Sections 21 through 26 contain additional guidelines for hog slaughter operations; and
* Section 27 contains additional guidelines for equine slaughter operations.

Note: The guidelines in this chapter are in addition to Chapters 1 through 8 which contain general guidelines which apply to all official meat and poultry establishments.

Meat Slaughter—General Facilities Guidelines

The following guidelines apply to all establishments that slaughter cattle, calves, sheep, goats, hogs and equines. If you are building or modifying an establishment that slaughters these species, consider these facilities guidelines to prevent contamination of carcasses during slaughter operations.

1. Livestock Pens

In addition to preventing contamination of the slaughter department and minimizing contaminates on the hides of the animals, proper design and construction of livestock pens prevent injury to the animals. Consider the following facilities guidelines when designing and constructing livestock pens:

* Livestock pens should be located outside the slaughter department to prevent contamination of products from dust, odors, and other contaminates. If possible, the livestock pens should be separated from the department by full-height partitions of impervious material.
* Livestock pens, driveways, and ramps should be free from sharp or protruding objects which could cause injury or pain to the animals.
* Floors of the pens, ramps, unloading chutes, and runways should be constructed to provide good footing for livestock. Waffled floor surfaces and cleated ramps are effective construction designs.
* Floors of the pens, ramps, unloading chutes, and runways should be sloped for drainage and cleaning.
* Pen enclosures (except gateways) should be high and sturdy enough to prevent livestock from escaping.
* Gates, fences, and chutes should have smooth surfaces that are easily cleaned.
* Man gates or, if the walls are concrete, toe holds formed in the walls should be present to allow people to escape from pen enclosures in an emergency.
* To help prevent livestock from slipping and falling on floors covered with excess water, thereby further contaminating their hides, water troughs should be provided with overflows located above or adjacent to pen floor drains.
* Hose connections should be provided for cleanups.
* Covered pens should be provided to protect crippled or downer animals from adverse climatic conditions. If held overnight, the pens should be large enough to allow the animals to lie down and have facilities for feed and water. Pens and driveways should be arranged so that sharp corners and direction reversals of driven animals are minimized.
* A ''U.S. suspect'' or ''U.S. condemned'' pen should be available at all times and designed to allow for complete separation, including the drainage system, from other livestock.

2. Ante-mortem Inspection Areas

Ante-mortem inspection areas should be designed and constructed to facilitate inspection and to prevent animals from being injured. Consider the following guidelines in designing and constructing these areas:

* To avoid delays in slaughter operations, pens for ante-mortem inspection should have the capacity for holding the maximum number of animals of the various species that will be slaughtered in a single day.
* To facilitate the ante-mortem inspection of animals, a separate suspect pen with a squeeze chute should be provided, where the temperature of the animals may be taken.
* At least 50 percent of the livestock pen, including the area where the suspect pen and squeeze chute are located, should be under a weather tight roof to provide an area for proper ante-mortem inspection in inclement weather.
* Special consideration should be given to designing ante-mortem inspection facilities to allow for humane transporting of crippled or downer animals into the slaughtering department. Because crippled and downer animals have difficulty moving,

special doorways and hoists to transport them to the stunning area should be provided.

3. Slaughter Area

The slaughter area is one of the most difficult areas to keep sanitary because of the nature of slaughter operations. Consider the following guidelines in designing and constructing slaughter areas to minimize contamination of carcasses:

* The slaughter area should be separated from the outside by a full-height partition or wall made of impervious material.

* Any doors to the outside of the slaughter area should be self closing to minimize the risk of contamination, including contamination by vermin.

* Slaughter areas should have floor space arranged to facilitate the sanitary conduct of operations and efficient inspection. For example, to prevent contamination of carcasses, truckways through which products are conveyed from the slaughter area to rooms such as the offal cooler, should be located so that the material is not trucked beneath rails from which dressed carcasses and products are suspended. For the same reason, personnel traffic should not move through lines of carcasses.

4. Stunning Areas Including Chutes and Alleys

Stunning areas, chutes and alleys, should be designed to prevent congestion, injury to animals, and minimize contamination of hides which can lead to contamination of the carcasses. Consider the following guidelines when designing these facilities:

* All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be large enough for the species being slaughtered.

* All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be free from pain-producing restraining devices, sharp projections such as loose boards, exposed bolt ends, splintered or broken planking, protruding metal, and exposed wheels or gears.

* All pathways, chutes, and alleys leading to stunning areas, and the stunning areas, should be free of unnecessary holes and openings where the animals' feet or legs may be injured.

* Overhead gates should be covered at the bottom edge to prevent, injury to the animals.

* Flooring should be constructed of roughened or cleated cement to reduce falls.

* Stunning areas should be provided for confining animals for stunning before bleeding.

* If ritualistic slaughter operations are conducted in the stunning area, shackles to confine the animals also should be provided.

* When captive bolt stunners are used, the stunning areas should be designed and constructed to limit the free movements of animals so that the operator can locate the stunning blow with a high degree of accuracy.

* When electrical stunning is used, the stunning area should be constructed so that any power activated gates will not cause injury to the animals.

5. Rail Arrangement and Truckways

To prevent contamination of carcasses, rails should be arranged to provide enough room for carcasses to move without touching equipment, walls, columns, other fixed parts of the building, and other carcasses. Consider the following guidelines when arranging rails in your establishment:

* Consideration should be given to the type of rail and the rail speed when determining how rails are to be arranged.

* Trim rails should be arranged so that carcasses pass the final carcass inspection position after the final trim.

* To prevent the carcass from becoming contaminated by debris on the floor and from splashes during cleanups, the cooler rails should provide for clearance from the lowest part of the carcass to the highest point of the floor.

* A room or area for washing gambrels, hooks, and trolleys should be provided. The room or area should have an exhaust fan in an outside wall to dispense steam.

6. Viscera Separation and Edible Byproducts Refrigeration

Because edible organs and parts (offal) are handled at temperatures conducive to bacterial growth, care must be taken in providing facilities for separation of viscera and for refrigeration of edible byproducts to prevent them from becoming contaminated. Consider the following guidelines for holding edible by products:

* Facilities, such as viscera trucks or pans, should be provided for separating and handling viscera of the various species of animals to prevent commingling.

* To prevent cross contamination, a separate cooler or a separately drained part of a carcass cooler should be provided for holding edible organs and parts (offal) under refrigeration.

* To convey the edible byproducts to a cooler, a truck with removable metal drip pans should be provided.

* To prevent cross contamination, establishment and inspection personnel from the slaughter department should be able to access the edible byproduct cooler without passing through a line of carcasses or through a congested carcass cooler.

7. Carcass Washing

Special facilities for washing inspected carcasses are needed to remove bone dust and other accidental contamination from the carcass. Consider the following guidelines when designing and constructing this area:

* A separately drained area or an area that is sloped to a floor drain should be provided where inspected carcasses are washed.

* If the carcasses are washed manually by establishment personnel, a platform should be provided to allow establishment personnel to be able to reach all parts of the carcass.

8. Retain Room/Compartment

* A retain room, cage, compartment, or receptacle may be required by inspection. Depending on the needs of inspection, consider the following guidelines for designing and constructing this room:

* The retain room or compartment must be equipped for locking or sealing.

* The room or compartment needs to be marked conspicuously ''U.S. Retained.''

* If the retain compartment is located in the cooler, the compartment should be separated from the remainder of the cooler to prevent cross-contamination of inspected and passed carcasses. The separation can be accomplished by creating a compartment constructed of partitions of corrosion resistant wire screen or flat expanded metal.

Cattle—Additional Facilities Guidelines

In addition to the guidelines (sections 1 through 8) for all establishments that slaughter livestock, the guidelines in the following sections 9 through 19 apply to establishments that slaughter cattle.

9. Cattle Dressing Layout

There are a number of different cattle dressing layouts that can be used in a cattle slaughtering operation. Depending on the number of animals slaughtered, rate of inspection, and number of inspectors, you should carefully consider your options for a layout for slaughter operations.

10. Rail Heights, Distances, and other Slaughter Area Dimensions

To assist you in planning the layout of your slaughter area, the following is a chart for recommended distances including rail heights, rail distances, and other cattle slaughter area dimensions:

TABLE 3.—GUIDELINES FOR DISTANCES IN CATTLE SLAUGHTERING ESTABLISHMENTS

Item	Vertical distance	Horizontal distance
Bleeding rail (distance from rail to point of application of shackle to shackle foot—4 feet (1.2 m)).	16 feet (4.9 m)	
Dressing rails (trolley length—1 foot 3 inches. (.4 m))	12 feet 3 inches (3.7 m)	
Beef cooler rails (trolley length—1 foot 3 inches. (.4 m))	11 feet (3.4 m)	
Moving equipment—heights of conveyor rails, platforms, top of viscera inspection table.		
Dry landing area in front of stunning pen.		7 by 8 feet (2.1 by 2.5 m)
Curb of bleeding area to pitch plates (no header rails).		5 feet (1.5 m)
Between header rail and carcass washing rail, if parallel.		6 feet (1.8 m)
Between header or washing rails and wall of slaughtering room.		3 feet (.9 m)
Between center lines of dressing beds.		8 feet (2.5 m)
Between moving top table and dressing rail at inspector's platform.		5 feet 6 inches (1.7 m)
Area for sterilizing viscera inspection truck.		7 by 8 feet (2.1 by 2.5 m)

Note.—When rails are involved in horizontal distance measurements, the distance is measured from the center of the rail. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

11. Dry Landing Area

A dry landing area large enough to accommodate stunned animals removed from the stunning pen should be provided adjacent to the stunning pen. Consider the following guidelines in designing and constructing this area:

* The area should allow enough room for the livestock.

* The dry landing area should be located and drained separately from the bleeding area.

* The dry landing area should be enclosed by a fence high enough and sturdy enough to prevent escape of inadequately stunned animals.

12. Bleeding Area

To contain blood and prevent it from contaminating carcasses, a curbed bleeding area should be provided. Consider the following guidelines in designing and constructing this area:

* The bleeding area should be located so that blood will not be splashed on stunned animals lying in the dry landing area or on carcasses being skinned on the cradle beds, if they are used.

* The curb around the bleeding area should be located far enough from the dressing bed or cradle to allow room for the carcasses to be maneuvered into the bed or cradle.

13. Facilities for Head Removal

To avoid contamination of the carcasses from rumen contents, facilities for head removal need to be carefully designed:

* Space should be provided for dehorning, flushing, washing, and inspecting heads; for storing heads on racks or trucks after removal from carcasses; and for head workup.

* When a down hide puller is used, the head drop and head removal area should be curbed and drained.

* A head wash cabinet should be provided.

14. Facilities for Hide Removal

To limit contamination by hides, a hide chute should be provided near the point where hides are removed from carcasses. Consider the following guidelines when designing and constructing these facilities:

* The chute should have a hood of sturdy rust-resistant metal with a push-in door closely fitting a metal frame inclined so as to be self-closing. In order to evacuate airborne contaminants from hides such as scurf, dirt, spores, odors, and hairs, a vent pipe should extend from the hood vertically to a point above the roof.

* Space needs to be provided between hide pulling and carcass evisceration to permit cervical inspection prior to viscera inspection.

15. Facilities for Feet and Udders

Because of the high risk of contamination of carcasses from feet and udders which have been removed from carcasses, special facilities, such as a chute or slide, should be used for transferring these parts to containers. Consider the following guidelines for these facilities:

* A chute or slide should be used to avoid splashing of milk or other contaminants onto the carcasses, floor, equipment, and personnel.

16. Foot Platforms

Foot platforms installed for establishment employees performing various carcass dressing operations need to be carefully designed and installed to prevent contamination of carcasses. Consider the following guidelines:

* If elevated foot platforms are used, they should be located so they do not touch skinned portions of the carcass.

* If stationary platforms are used, they should be set far enough away from the dressing rail to prevent contact with the forelegs of cattle.

* To provide space for operations and to prevent cross contamination by carcasses, push fingers or rail stops on powered conveyor or gravity flow rails should be spaced far enough apart to prevent contact between carcasses.

17. Viscera Trucks

In establishments with a limited rate of slaughter, viscera are usually placed in a specially designed handtruck for inspection. Consider the following guidelines for use of viscera trucks:

* For ease of cleaning, viscera trucks should be constructed of stainless or galvanized steel.

* Viscera trucks should have an inspection pan and a lower viscera compartment.

* When viscera trucks are used, a separately drained area should be available for washing and sterilizing such equipment.

* To prevent contamination of products, the washing facilities should be located at or near the point where condemned products are discharged from the trucks. When placed where splash might contaminate edible products, the truck washing area should have walls high enough to contain any splash.

18. Moving-Top Inspection Tables

In some establishments, viscera are placed on a moving-top table for inspection. These tables have special considerations as follows:

* The table should be of a length that provides for evisceration, inspection, and viscera removal.

* A continuous cleaning and sanitizing system should be available for the table.

* To prevent contamination of products and the surrounding area, the viscera inspection table should have a drain under the table to prevent water from draining across the floor to other areas of the room.

* To prevent contamination of carcasses, the foot platform, handwash sinks, hand tool disinfection unit (sterilizer), boot washing cabinet, and boot storage locker should be located alongside the loading end of the table.

19. USDA Post-mortem Inspection Station and Retain Rail

Special facilities are needed for USDA post-mortem inspection for cattle. Consider the following provisions that must be met when designing these stations:

* An inspection station consisting of 5 feet (1.5 m) of unobstructed line space for each head or carcass inspector.

* When viscera tables are used, there must be 8 feet (2.5 m) for each viscera inspector on the inspector's side of the table needs to be provided.

* A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass.

* A handwash sink (other than one which is hand operated), furnished with soap, towels, and hot and cold water, and located adjacent to the inspector's work area.

* For each head and viscera inspector on cattle slaughter lines a sterilizer located adjacent to the inspector's work area.

* For mechanized operations, a line control switch adjacent to each inspection station.

* Facilities to position tally sheets or other recording devices, such as digital counters and facilities to contain USDA condemned brands.

* Rail(s) for holding retained carcasses for final disposition along with platforms and handwash sinks. To prevent possible cross contamination, the retain rail must be long enough to prevent carcasses from touching.

20. Calves, Sheep, and Goats—Chart of Guidelines for Distances for Rails and Other Facilities

TABLE 4.—GUIDELINES FOR DISTANCES IN CALF, SHEEP, AND GOAT SLAUGHTERING ESTABLISHMENTS

Item	Vertical distance	Horizontal distance
Bleeding rail for calves (distance from top of rail to point of application of shackle to shackled foot—2 feet 6 inches (.8 m)).	11 feet (3.3 m)	
Bleeding rails if only sheep or goats are slaughtered	9 feet–11 feet (2.7 m–3.4 m)	
Dressing rail (trolley length—1 foot (.3 m))	8 feet 6 inches (2.6 m)	
Cooler rails, calf carcasses (trolley length—1 foot (.3 m)).	8 feet 6 inches (2.6 m)	
Cooler rails, sheep or goat carcasses (trolley length—1 foot (.3 m)).	7 feet 6 inches–8 feet 6 inches (2.3 m–2.6 m).	
Moving equipment		
Vertical of rail to edge of viscera inspection stand		2 feet (.6 m)
Length of rail from point of evisceration to point where carcass inspection is completed.		6 feet (1.8 m)

Note.—When rails are involved in horizontal distance measurements, the distance is measured from the center of the rail. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

Hogs—Additional Facilities Guidelines

In addition to the general guidelines in sections 1 through 8, the following guidelines apply to those establishments that slaughter hogs. Consider these additional guidelines when building or modifying an establishment that slaughters hogs.

21. Livestock Pens

* To prevent hogs from overheating, pens for hogs should have either a roof for shelter or a shower system to keep the animals cool in weather with temperatures greater than 70 °F (21 °C).

22. Location of Certain Operations

* To prevent contamination, the following equipment and operations should be located in an area or areas separate from the carcass dressing area, except for the openings for access and passage of carcasses:

** Hoisting, sticking, and bleeding.

** Scalding vat.

** Dehairing machine located within a curbed area having nonclogging drainage outlet.

** Gambrelling table.

** Singeing operations.

23. Rail Arrangements for Hogs

The following chart gives guidance for recommended distances for rails and other facilities for hog slaughter operations.

TABLE 5.—GUIDELINES FOR DISTANCES IN HOG SLAUGHTERING ESTABLISHMENTS

Item	Vertical distance
Bleeding rail to sticker's platform.	10 feet 6 inches (3.2 m).
Extension of bleeding rail to top of scalding vat.	9 feet (2.7 m).
Dressing rails [1]	11 feet (3.3 m).
Gambrels (suspending carcasses to floor (1 foot (.3 m)).	10 feet (3 m).
Distances from rail to bottom of inspection pans and various foot platforms.	
Rails in coolers for hog carcasses with heads removed (1 foot (.3 m)).	9 feet (2.7 m).
Rails to coolers for carcasses with heads attached (1 foot (3 m)).	10 feet (3 m).
Vertical of dressing rail to various foot platforms and widths of platforms.	

[1] Heads dropped but still attached.

Note.—When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

24. Scalding

To avoid contamination of the carcass, a scalding tank is used to remove hair and other contaminants.

Consider the following when installing a scalding tank:

* A mechanical exhaust fan above the scalding tank will disperse steam.

25. Shaving, Singeing, and Carcass Washing

* A shaving rail (throw-out rail) should be provided prior to the head dropping operation, so that unclean hogs can be removed from the dressing line for cleaning.

* If a singer is used to remove hair, it should have an automatic cut off and starter switch to prevent the carcass from burning when the chain stops.

* If a polisher is used, water sprays to clean the carcass of hair should be provided.

* To remove hair from the hide which was missed by the scalder and dehairing process, a carcass washer should be located at a point after completion of shaving operations and before the head dropper's station.

26. Inspection Facilities

Special facilities are needed for USDA post-mortem inspection for swine. Consider the following guidelines when designing these stations:

* An inspection station consisting of 5 feet (1.5 m) of unobstructed line space for each head or carcass inspector must be provided.

* When viscera tables are used, there must be 8 feet (2.5 m) for each viscera inspector on the inspector's side of the table needs to be provided.

* A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass must be provided.

* A handwash sink (other than one which is hand operated), furnished with soap, towels, and hot and cold water, must be provided adjacent to the inspector's work area.

* For each head inspector on swine slaughter lines, a sterilizer must be located adjacent to the inspector's work area.

* For mechanized operations, a line control switch must be provided adjacent to each inspection station.

* For swine slaughter lines requiring three or more inspectors, and for those one-and two-inspector configurations where the establishment installs a mirror, special facilities are needed. At the carcass inspection station one glass or plastic, distortion-free mirror, at least five by 5 feet (1.5 by 1.5 m), must be mounted at the carcass inspection station. The mirror should be mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet (90 cm) away, to allow any inspector standing at the carcass inspection station to readily view the back of the carcass.

* Facilities to position tally sheets or other recording devices, such as digital counters and facilities to contain USDA condemned brands must be provided.

Equines—Additional Facilities

In addition to the general guidelines in sections 1 through 8, and the guidelines for cattle in sections 9–19, if you plan to slaughter equines, such as horses, mules, donkeys, and ponies, the following are additional guidelines when building or modifying equine slaughter facilities.

27. Equine Slaughter Facilities

* The facilities for equine slaughter establishments are essentially the same as those for slaughtering cattle. Exceptions include the following rail heights and clearances.

TABLE 6.—GUIDELINES FOR DISTANCES IN EQUINE SLAUGHTERING ESTABLISHMENTS

Items	Vertical distance	Horizontal distance
Bleeding rail	18 feet (5.5 m)	
Dressing rails (trolley length—1 foot 3 inches (.4 m)).	12 feet 6 inches (3.8 m)	
Cooler rails (trolley length—1 foot 3 inches (.4 m)).	12 feet 6 inches (3.8 m)	
Cooler rails for carcasses in quarters.	8 feet 6 inches (2.6 m)	
Line of drop-offs to line of half hoists.		17 feet (5.2 m)
Clearance between walls, posts, etc. and adjoining rails in slaughter rooms and coolers.		3 feet (.9 m)
Curb of bleeding area to pritch plates.		6 feet (1.8 m)
Dry landing area (minimum).		7 by 8 feet (2.1 by 2.5 m)

Note.—When rails are involved in horizontal distance measurements, the distance is measured from the center of the rail. When rails are involved in vertical distance measurements, the distance is measured from the top of the rail to the highest part of the floor.

Chapter 10

POULTRY SLAUGHTER ESTABLISHMENTS

Although the flesh of healthy living poultry is practically sterile, when the bird is killed many factors can contribute to contamination of the carcass including improperly designed and constructed slaughter facilities. This chapter provides guidelines for facilities for poultry slaughter establishments for you to consider in building or modifying your slaughter facilities. If you slaughter small animals such as rabbits or migratory fowl under voluntary inspection, use this chapter for guidance. See Chapters 1 through 8 for general information which applies to all official meat and poultry establishments.

1. Holding Sheds or Coops

When building holding sheds or coops for poultry, consider the following guidelines:

* A minimum of 30 foot candles of lighting must be provided to facilitate ante-mortem inspection.

* The holding sheds should be weather tight.

2. Docks for Receiving and Hanging Live Poultry

Consider the following guidelines to prevent dust, feathers, and other obnoxious substances from entering areas where edible products are being prepared, handled, or stored:

* The live hanging dock needs to be physically separated from these areas. The separation should be accomplished by full height impervious walls with self-closing impervious doors, and openings limited to that necessary for poultry conveyor systems.

3. Slaughter Area

Consider the following guidelines for the slaughter area to minimize risk of contamination to products:

* The slaughter area (including stunning, bleeding, picking, scalding, and eviscerating operations) should be separated from those areas of the establishment where edible products are prepared or stored to minimize the risk of contamination.

* The blood in the slaughtering area, especially the stunning and bleeding area, should be contained in as small an area as possible.

4. USDA Post-Mortem Inspection Station

There are four systems of post-mortem inspection: Traditional Inspection, the Streamlined Inspection System, the New Line Speed Inspection System, and the New Turkey Inspection System. Each of the systems has mandatory requirements to minimize the risk of contamination to products and to promote efficient inspection. However, with the exception of the lighting requirements, there are no facilities guidelines for these post-mortem systems.

5. Facility Guidelines for Poultry Inspection Stations

Note: There are no facility guidelines for Traditional Inspection System facilities except for lighting.

TABLE 7.—FACILITY GUIDELINES FOR POULTRY INSPECTION STATIONS

Facility	SIS	NELS	NTI
The conveyor line should be level for the entire length of the inspection station	X	X	X
The vertical distance from the bottom of the shackles to the top of the adjustable inspection platform, when it is set in its lowest position, should be a minimum of 60 inches (150 cm)	X	X	X
There should be a minimum of 8 feet (2.5 m) of space along the conveyor line for one inspection station and 16 feet (4.9 m) for two inspection stations	X		X
There should be a minimum of 42 feet (12.8 m) of space along the conveyor line for three inspection stations		X	
There should be a minimum of 6 feet (1.8 m) of space along the conveyor line for the establishment employee presenting the birds		X	
There should be a minimum of 4 feet (1.2 m) of space for inspector and a minimum of 4 feet (1.2 m) of space for the establishment helper along the conveyor line	X	X	X
There should be selectors or ''kick-outs'' with birds on shackles with 12 inch (30 cm) centers (two inspection stations on line)	X		
There should to be selectors or ''kick-outs'' with birds on shackles with 18 inch (45 cm) centers (three inspection stations on line)		X	
A distortion-free mirror should be located at each inspection station which is: at least 3 feet (.9 m) wide and 2 feet (.6 m) high; adjustable between 5 inches (12.5 cm) and 15 inches (38 cm) behind the shackles; positioned in relation to the inspection platform so that the inspector is positioned opposite it 8 to 12 inches (20.3 cm to 30.5 cm) from the downstream edge; installed so that guide bars do not extend in front of the inspection mirror; and illuminated by a light which is positioned above and slightly in front of the mirror to facilitate the illumination of the bird and mirror surface		X	
There should be a slip-resistant inspection platform with a 42 inch (105 cm) high rail on the back side and with ½ inch (4 cm) foot bumpers on both sides and front	X	X	X
There should be an inspection platform with a minimum length of 4 feet (1.2 m) and minimum width of 2 feet (.6 m)	X	X	X
There should be an adjustable inspection platform that easily and rapidly adjusts a minimum of 14 inches (35 cm) vertically while standing	X	X	X
A trough or other facilities extending beneath the conveyor where processing operations are conducted from carcass opening to trimming should be provided which is wide enough to prevent trimmings, drippings, and other debris from accumulation on the floor or platform; and has enough clearance between suspended carcasses and the trough to prevent contamination of carcasses by splash	X	X	X
A conveyor line stop/start switch should be provided at each inspection station within easy reach of the inspector	X	X	X
A minimum of 200-foot candles of shadow-free lighting with minimum CRI value of 85, which can be met by deluxe cool fluorescent lighting, must be provided	X	X	X
Online hand rinsing facilities with continuous flow water withineasy reach should be provided for each inspector and establishment helper	X	X	X
Online hand rinsing facilities with continuous flow water within easy reach must be provided for each establishment presenter		X	
Receptacles for condemned carcasses and parts should be provided at each inspection station	X	X	X
Hang-back racks should be provided and located within easy reach for establishment helpers	X	X	X

6. Facility Guidelines for Poultry Reinspection Stations

Note: There are no guidelines for Traditional Inspection System facilities except for lighting.

TABLE 8.—FACILITY GUIDELINES FOR POULTRY REINSPECTION STATIONS

Facility	Prechill and postchill reinspection stations	Reinspection stations	
	SIS	NELS	NTI
There should be a minimum of 6 feet (1.8 m) of space along the conveyor line for the establishment presenter		X	
There should be a minimum of 3 feet (.9 m) of space along each conveyor line and for SIS after each chiller	X		X

TABLE 8.—FACILITY GUIDELINES FOR POULTRY REINSPECTION STATIONS—Continued

Facility	Prechill and postchill reinspection stations	Reinspection stations	
	SIS	NELS	NTI
A table for reinspecting sample birds should be provided which is at least 2 feet (.6 m) wide, 2 feet (.6 m) deep, and 3 feet (.9 m) high; readily cleanable; and drainable	X		
A table for reinspecting sample birds should be provided which is at least 3 feet (.9 m) wide and 2 feet (.6 m) deep; readily cleanable; and drainable		X	X
A space which is level and protected from all traffic and overhead obstructions should be provided	X	X	X
The vertical distance from the bottom of the shackles to floor needs to be a minimum of 48 inches (120 cm) should be provided	X	X	X
A minimum of 200-foot candles of shadow-free lighting with a minimum CRI of 85 at the table surface, which can be met by deluxe cool white fluorescent lighting, must be provided	X	X	X
A separate clipboard holder for holding the recording sheets should be provided	X	X	X
Handwash sinks within easy access of all persons working at the station should be provided	X	X	X
Hang-back racks should be provided which are within easy reach of all persons working at the station, and designed to hold 10 carcasses	X	X	X

7. Evisceration and Reprocessing Areas

The evisceration area should be arranged to facilitate efficient sanitary operations and inspection. Consider the following guidelines when designing these areas:

* Production lines should have drip pans installed beneath them, when these lines are located above areas such as walkways, truckways, work stations, and equipment, to prevent water, poultry products, or any other material from falling on the production areas below.

* An area should be provided for a reprocessing station for the reconditioning of retained products including removal of contamination.

8. Inedible Offal

In poultry establishments, the facilities for handling inedible offal should be designed to accommodate the size of the poultry being handled and to prevent the contamination of edible products. Consider the following guidelines when designing these areas:

* The facilities, whether troughs or otherwise, should be large enough to allow clean and orderly removal of inedible offal during processing, without a pile up and without cross contamination of edible products.

* The water rail for semi-dry poultry offal systems for young chickens should range from 34 to 36 inches (86 to 90 cm) in height above the standing surface and be positioned 7 to 10 inches (18 to 26 cm) horizontally from the vertical line of the shackle.

* The water rail for semi-dry poultry offal systems for turkeys should range from 34 to 36 inches (86 to 90 cm) in height above the standing surface and be positioned 13 to 15 inches (33 to 38 cm) horizontally from the vertical line of the shackle.

* The floor gutter should be distinct, with vertical sides inside the post supporting the water rail (a minimum of 6 inches or 15 cm is suggested to prevent workers feet from being in the gutter). Gutters should also be wide enough to catch all material dropping from the carcass.

* Splash protectors should be installed at all points along the evisceration line where splashing of employees might occur.

* Pipes for conveying offal should be constructed to permit daily cleaning and positioned so that sanitation will not be a problem, i.e., no pipes lying on the floor or bottom of a gutter.

* Side walls of hoppers should be pitched to assure that material deposited in the hopper will slide to the point where the offal is being mechanically conveyed.

Chapter 11

PLANT WASTE DISPOSAL

Control and disposal of plant wastes are major concerns. Optimum use and reduction of waste are essential goals of economic production in all plants. From a plant sanitation standpoint, there are two vital concerns with waste disposal: (1) Plant waste contains most of the contaminants and disease-producing and product-spoiling microorganisms from the plant production processes; (2) plant wastes attract pests such as insects and rodents.

1. Organic Waste Disposal

When disposing of organic wastes such as feathers, viscera, blood, and manure, the following guidelines should be considered:

* Waste materials should not be allowed to accumulate on or near the premises.

* Waste should be disposed of without creating insanitary or objectionable conditions.

* Waste should be removed daily.

* Holding bins should be cleaned before reuse and protected from insect and rodent harborage and infestations.

2. Rubbish Removal

Rubbish, such as paper towels, cartons, office waste, and labeling materials, can become a sanitation problem. The following guidelines should be followed when removing rubbish:

* Suitable containers should be conveniently located throughout the plant and emptied frequently.

* The accumulation of rubbish before its removal should not cause a nuisance.

* Plant refuse should be removed daily, or more often if necessary, to prevent a nuisance.

Appendix B—Guidelines for Developing Partial Quality Control Programs (PQC's)

Guidelines for Developing Partial Quality Control Programs Overview

Quality control programs are essential to the proper functioning of any meat or poultry processing establishment. Processors have found quality control is good business because it can reduce costs, control product uniformity, and ensure that proper standards are being maintained throughout the production cycle. By increasing controls over raw ingredients, processes, and other variables, effective quality control systems can ensure compliance with company specifications and with the guidelines and requirements of the Department of Agriculture. Although in-plant inspectors have a role in the oversight of these programs, quality control is a management function and plant management should develop and implement effective quality control plans specific to their process and products.

There are many approaches plants can take to ensure quality control. Some plants do not take any special measures during production, and changes are made only on finished product. Some plants incorporate preventive measures, such as product testing, during processing, and others undertake a series of specific actions to prevent mistakes and to ensure that products meet consumer expectations. Whether

limited or comprehensive, a quality control system should be in the written record of the plant. As experience is gained, the record keeping system may be improved by focusing on ''hot spots'' which are responsible for the major problems, revising specifications, or upgrading them to include sensitive testing devices, for example.

Proper documentation of plant activities will become increasingly important in a HACCP inspection environment. Proper documentation of any in-plant process can save time and money and result in fewer mistakes by the establishment. The degree and complexity of the records depend on the scope of the processing operation; completeness of the records is also a reflection of management commitment to quality control.

Plant or corporate management support is the key to a successful quality control program. Plant personnel will sense a lack of commitment to quality if management support is not apparent.

Good quality control managers do not necessarily have to use complex, expensive methods to ensure control. Experience has shown that successful establishments function smoothly by paying close attention to the basics, documenting the process when it is running smoothly and when problems occur, and making necessary corrections as quickly as possible.

Chapter 1. Introduction

Title 9 of the Code of Federal Regulations at Parts 318.4(d) and 381.145(d) require Federal meat and poultry processing plants to establish and maintain written records for each critical check or critical control point and make the records available to FSIS inspection personnel upon request.

* Although the regulatory requirement for FSIS to review and approve PQC programs has been rescinded, the new regulatory requirements in 318.4(d) and 381.145(d) provide information to plants about the necessary steps they must take to meet the new record keeping requirements in a Pathogen Reduction and HACCP inspection environment.

* FSIS will continue to provide guidance to establishments to ensure that their Partial Quality Control (PQC) programs for specific products and processes are adequate to ensure product compliance with regulatory requirements. The information in this document is intended to be used as guidance material and is based on FSIS' experience and historical perspective reviewing and approving PQC programs.

A few model PQC programs, representative of many products and processes, are presented below.

Chapter 2. Components of PQC Programs

PQC programs should address four areas: (1) raw materials control; (2) process control; (3) records control; and (4) corrective/preventive action.

1. Raw Materials Control

Raw materials control involves the receiving and stocking of only those materials that conform to established specifications. To ensure successful control of raw materials, establishments should consider the following:

* To begin the development of a raw materials control procedure, plants should list each of the materials used to produce the product.

* Once the list has been created, establishments should develop a receiving inspection procedure.

* The procedure may address raw materials specifications, proper materials handling, proper storage, and disposal of nonconforming materials.

* Materials should be routinely monitored to ensure they are meeting the established procedures.

2. Process Control

Process control programs ensure continuous control of particular processes so that product standards will be met. Process control programs should meet the following criteria:

* They should identify the products or processes to be controlled.

* They should identify the control features necessary for product compliance.

* They should establish control limits.

* They should establish procedures for meeting the established limits.

* They should provide monitoring procedures for ensuring that procedures are followed.

An important aspect of process control is effective data collection and analysis. Process control programs should include sampling plans that permit reliable collection and analysis of data. After sampling plans have been developed, process limits can be established.

* The limits established should be appropriate to ensure that quality standards will be met.

* The limits established should be appropriate to ensure that meet regulatory or label limits for the product or process will be met.

* Variation in materials, methods, processes, and products requires the setting of a tolerance for each quality standard. A tolerance limit is the total allowable deviation from an established standard. The limit allows for the normal variability which is inherent in any process.

* Tolerance limits may need to be continuously adjusted to prevent problems.

* Limits for certain processes have been established and used historically by industry; these limits are reflected in PQC programs previously approved by FSIS. The tolerances meet the intent of the requirements in 318.4(d) and 318.145(d)(2)(ii) and may continue to be used.

* Establishments may elect to use these previously established tolerances or develop their own by following the requirements outlined in the regulation.

3. Records

An important aspect of quality control is process documentation. Adequate records are essential to the system's capacity to provide the necessary controls. The records provide a history of the process and document when the process is working and when problems are occurring. The use of standard sheets, check-off forms, and other simple records is generally more successful than a complicated system. Charts and graphs already in use may be all that is necessary to document the system. The degree of record keeping and the complexity of the records depend, in large part, on the scope of the processing operation. In reviewing records, plant management should:

* Look at those aspects of production most likely to cause problems. This procedure also can be useful in determining what critical checks need to be incorporated into a quality control program.

* Correct problems as they occur. Proper documentation of the process can save time and money because it provides an establishment an opportunity to correct a problem before the finished product has been completed.

4. Corrective/Preventive Action

Corrective action plans address the action to be taken when problems develop in a production process. Corrective action plans are essential components and important indicators of the strength of quality control programs. The primary emphasis of the plans should be on correction/prevention of problems in the production process. The type of plan used in a particular quality control program will be determined by the establishment and the processes conducted at the plant. Generally,

corrective action plans should include the following features:

* They should provide for the identification of problems or deviations in processes.

* They should provide for the identification of the causes of problems.

* They should specify the corrective steps to be initiated and the criteria for determining how noncompliant products should be handled.

* The plans should provide that corrective/preventive measures be implemented after a determination that no safety hazards exist.

* The plans should provide for documentation of the corrective and preventive measures taken.

Models

The following models are intended to be used as general guidelines to developers of quality control programs. They are not intended to be complete QC programs or a complete listing of all rotational QC programs but offer a framework and one approach to QC program development. In actual QC programs, details regarding tests, action criteria, corrective actions, and responsible personnel would reflect the specific process and establishment circumstances. Any specifications or limits cited are only examples and do not establish or imply Agency standards.

Model 1—Preparation of a PQC Program for the Addition of 10-Percent Solution to Poultry

Raw Material Control

* Poultry—Chicken breasts will be received frozen, examined for condition, and immediately placed in the receiving dock freezer. (Specifications to be set by establishment.)

* Dry ingredients—Upon receipt, the dry ingredients will be visually inspected for acceptance and immediately placed in the dry storage warehouse. (Specifications to be set by establishment.)

* Corrective action—If either the poultry or the dry ingredients is found to be unacceptable, it will be tagged immediately and Quality Control will be notified. QC will evaluate and initiate appropriate product disposition.

* Documentation—All critical checks and corrective actions will be recorded on the receiving log.

Process Control

* Formulation control.

** Formulation control—A pumping solution will be formulated according to the label formulation. One ingredient of the solution will be weighed by a quality control technician for each batch. If an ingredient is found to be m0ore than 0.5 percent above or below the weight stated on the formula, the following will result: (1) the problem will be evaluated and the appropriate corrective action taken; (2) each ingredient of every batch will be checked until five consecutive batches are found to be in compliance.

** Documentation—All formulation check results and corrective actions, if needed, will be recorded on the formulation log.

** Scale accuracy control.

*** Scale checks—All scales associated with the pumping operation will be verified for accuracy before operations begin. Scale accuracy will be checked against a known weight. If a scale is found to be inaccurate, it will not be used until it has been calibrated.

*** Documentation—All scale check results and corrective actions, if required, will be recorded on the scale maintenance record.

Lotting

* A lot will be defined as one shift's production; a sublot as approximately 500 pounds of product.

Added Solutions

* Green weight determination—Each sublot will be identified with a unique code representing date and time of day the sublot is being produced.

** The sublot will be weighed before pumping.

** The identifying code and weight will be written on a tag, which will be attached to the combo bin containing the sublot.

* Pumping—Every 30 minutes, 10 turkey breasts will be selected from a sublot before it is pumped. The 10 turkey breasts will be weighed, then passed through the pumping machine. The turkey breasts will be allowed to drain for 5 minutes, then weighed again.

** Tolerances—Each pump check will not be more than 0.5 percent over the target pump of 10 percent. If a pump check is found to exceed the tolerance, all product back the last pump check will be retained and allowed to drain until it reaches the target pump. In addition, the pumping operations will be stopped, evaluated by a QC technician, and not allowed to start until the problem has been corrected.

** Documentation—All pump checks and corrective actions, if needed, will be documented in the pumping log book.

* Finished weight determination—After a sublot has been pumped, a final weight will be obtained and recorded on the pumping tag.

** Tolerances—No sublot will be more than 1.2 percent above the target pump of 10 percent. The average of all sublots will meet the target pump. If any sublot or the average of the sublots exceeds tolerances, all product will be retained and allowed to drain until the target pump has been reached.

** Documentation—All green weights, finished product weights, and corrective actions, if needed, will be recorded in the finished product log book.

Note: Model also can be used in developing the following PQC programs:

Percent Labeling Control
Water-misted/Ice-glazed Meat and Poultry Products
Addition of Solution to Raw/Cooked Meat and Poultry Products (Injection, Massaging, Tumbling, Basting, Marination, and Tenderization)
Fat and/or added water for Raw Product

Model 2.. Preparation of a PQC Program for Fat-Content-per-Serving Labeling for Meat and Non-Meat Products

Scales/Meters

* Establish verification procedures to ensure that all scales/meters used in the formulation and analytical testing of the product are accurate. The procedure should include checks against a standard weight or measurement.

Lotting

* Define lot and sublot.

* Establish a standardized procedure for identifying the lot throughout the process.

Formulation

* Establish a procedure to verify the formulation of each lot/sublot in compliance with the approved label formulation.

* Establish tolerances for non-restricted ingredients.

* No ingredient in the formulation should be substituted for another.

Fat content of the meat portion (ground beef, ground pork, or products with a declared fat limit on the label)

* Establish a statistically sound sampling procedure for each lot/sublot of the meat portion.

* Identify the analytical method used, such as an AOAC method. Weight Control (serving and component).

* Establish a statistically sound sampling procedure to ensure that each portion and component of the product within a lot/sublot is checked against the label transmitted.

* Raw weights—The weight is checked on all portions and components on finished raw and cooked products.

* Cooked weights—Cooked weights are checked and compared with the portion size stated on the transmittal

and on the Child Nutrition (CN) label. Weights also are checked for precooked components of products against information on the label transmittal.

* The sampling plans and tolerances should be based on generally recognized statistical process control methods and should ensure that the process is in control and that applicable product or label limits are being met.

* Each CN product should have its own lot average.

Batter and Breading (if applicable)

* Establish a procedure to verify that the batter/breading application does not exceed regulatory limits, label declarations, or product standards. The monitoring procedure should identify the following:

** pre-batter/breading application weight

** sample size

** sample frequency

** post-batter/breading application weight

* Post-batter/breading weight should be determined at the end of the application procedure and before further processing. Note: Model also can be used in developing the following PQC programs:

Batter and Breading

FES Labeling Content for Meat and Non-Meat Products

Precooked Breakfast Sausage Yield Control

Model 3. Low Temperature Rendering for the Production of Partially Defatted Chopped (P.C.) Beef/Pork, Fat-Reduced Species, and Partially Defatted Beef/Pork Fatty Tissue

Raw Materials Control

* Define a lot and sublot

* If producing P.C. beef/pork or fat-reduced species, establish a statistically based sampling procedure to ensure the lot is in compliance with raw material requirements (12 percent lean).

Heat Processing

* Identify processing temperature (minimum and maximum).

* Identify the target processing time, which is the time the product is subjected to the target.

* Establish procedures for monitoring processing temperatures and times.

Cooling and Freezing Controls

* Identify the cooling and freezing temperatures for the finished product.

* Identify the amount of time the cooling and freezing process will take to reach established temperatures.

Microbiological

* If the cooling/freezing process (starting from the time heat is applied until the product is 40 degrees F for less) exceeds 30 minutes, a microbiological sampling procedure should be developed. The following sampling procedures and limits have been used in PQC programs in the past, and current regulations permit their continued use.

** Using a statistically based sampling plan, select two samples per lot from the raw material and finished products.

** Test samples for total plate count, coliforms, *E. coli,* and *C. Perfringens.*

** Demonstrate that the process does not increase the product's microbial load by 1 log or more.

** Sampling can be reduced to one per lot when control has been demonstrated in three consecutive lots.

Finished Product Controls

* If producing finely textured lean or finely textured extra lean, product should be tested for fat, protein, and protein efficiency ratio (PER) or essential amino acid (EAA).

* Incorporate the sampling procedure for fat and protein.

** Individual—Obtain a one-pound sample from each lot. After 10 consecutive analyses are in compliance with single sample limits, sampling may be reduced to one randomly sampled lot out of every three lots.

** Process Average—A process (moving) average of 10 lots should be maintained.

Sampling Procedures for PER/EAA

* Initially, each lot should be held and tested until compliance has been established. Once compliance has been established in three consecutive lots, sampling may be reduced. Sampling frequency should begin with at least one sample per month until compliance has been established. When three consecutive samples are in compliance, the frequency may be reduced to one sample every three months.

* Analytical Standard Limits

Finely Textured Lean Product

Individual;

Fat—Maximum 30%

Protein—Minimum 13%

Process Average:

Fat—Maximum 30%

Protein—Minimum 14%

PER 2.5 or

EAA 33%

Finely Textured Extra Lean Similar Products

Individual:

Fat—Maximum 11%

Protein—Minimum 13%

Process Average:

Fat—Maximum 10%

Protein—Minimum 14%

PER 2.5 or

EAA 33%

Corrective and Preventive Actions

* Develop corrective and preventive actions for each critical check point established.

Note: Model also can be used in developing the following PQC programs:

Low Temperature Rendering for Control of Partially Defatted Chopped Beef/Pork Fat-Reduced Species and Partially Defatted Beef/Pork Fatty Tissue

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BILLING CODE 3410–DM–P

Wyoming DEPARTMENT OF Agriculture

CONSUMER HEALTH SERVICES PLAN REVIEW PACKET

All facilities must be inspected and licensed prior to operation. Submitting this form does not give permission to open or operate an establishment.

To ensure a timely review, the following documents shall be submitted to the department for approval at least 30 days prior to construction

1. Completed Plan Review Packet
2. One complete set of floor plans, drawn to scale, showing layout of equipment and mechanical systems. Refer to Ch. 2, Sec. 7 of the Wyoming Food Safety Rule or Ch. 2 of the Wyoming Pool Rule
3. Refer to specific plan review packet for additional requested information

Once the plan review packet has been approved, a pre-opening inspection shall be completed, license application completed and fees paid to Wyoming Department of Agriculture before a license will be issued. A license fee of $100.00 will be required at time of licensing. Please make checks payable to: **Wyoming Department of Agriculture Consumer Health Services Section.**

Area inspector contact information and entire written regulations can be found at http://wyagric.state.wy.us/divisions/chs, or by contacting the Consumer Health Services Division of the Wyoming Department of Agriculture at 307-777-7211.

Mark All That Apply:

___ New construction
___ Conversion of an existing building
___ Remodeling
___ Change of type of operation
___ Change of ownership
___ Requested by regulatory authority

_____
Applicant's printed name & title:

_____
Applicant's signature date of signature

Date Plan Review Submitted: _____ Anticipated Opening Date: _____

Wyoming DEPARTMENT OF Agriculture

GENERAL INFORMATION

TYPE OF ESTABLISHMENT (CHECK ALL THAT APPLY)

☐ Aquatic Features	☐ Bulk Water	☐ Dairy	☐ Dietary Supplement	☐ Manufactured Food	☐ Meat Plant	☐ Mobile Unit or Push Cart	☐ Retail Food

Name of Establishment:	Phone:
Address:	Cell:
City:	Fax:
State/Zip:	Email:
County:	
Website:	

OWNERSHIP INFORMATION

Individual Name:	Phone:
Title:	Cell:
Corporate Name:	Fax::
Mailing Address:	
City:	Zip:
State:	Email:
Form of Organization:	Date formed and state where incorporated:
☐Individual ☐Association ☐Corporation ☐Partnership ☐Other entity:	

ON-SITE CONTACT INFORMATION (☐ CHECK IF SAME AS ABOVE)

Name of Primary Contact	Phone:
Address:	Cell:
City/State:	Zip:
Additional contact/title:	Phone:
Additional contact/title:	Phone:

DAYS AND HOUSE OF OPERATION

Days	☐ Sun	☐ Mon	☐ Tue	☐ Wed	☐ Thurs	☐ Fri	☐ Sat
Hours	to	to	to	to	to	to	to

Wyoming DEPARTMENT OF Agriculture

MONTHS OF OPERATIONS											
☐ Jan	☐ Feb	☐ Mar	☐ Apr	☐ May	☐ Jun	☐ Jul	☐ Aug	☐ Sept	☐ Oct	☐ Nov	☐ Dec
If a seasonal operation or irregular hours will occur, please explain:											

ADDITIONAL COMMENTS

FOR OFFICE USE ONLY
Date Plan Review Received: _____ _____ _____ _____ _____ _____
Plan Review Received by: _____
Date Plan was Reviewed: _____ _____ _____ _____ _____ _____
Approved: _____ **Denied:** _____
Comments:

Consumer Health Services
MEAT PLAN REVIEW WORKSHEET

This Plan Review is designed to be used by the meat plant establishment applicant/operator to make sure essential areas have been addressed/included in the plans submitted. It is not an all-inclusive list for the specific needs of each plant operator. In addition to this Plan Review additional content may be requested. Additional information and guidance can be found at https://wyagric.state.wy.us/divisions/chs/meat-a-poultry-program the eCFR can be located at:
https://www.ecfr.gov/cgi-bin/text-idx?SID=922017d43014111b0bee009e85821d89&mc=true&tpl=/ecfrbrowse/Title09/9tab_02.tpl

Below is a checklist of required information needed to complete the plan review. Please ensure all information in included. *Lack of complete information will delay review and plan approval.*			
☐	**Floor Plans/Specifications**	☐	**HACCP(s) Plan(s)** (State Inspection Only)
☐	**Water and Sewer Approval**	☐	**Pre-Shipment Review** (State Inspection Only)
☐	**Age Dentition**	☐	**SOP(s)**
☐	**Label Approval**	☐	**SSOP(s)** (State Inspection Only)
☐	**Letters of Guarantee**	☐	**GMP(s)** (State Inspection Only)
☐	**Source/Receiving**	☐	**Retail Grind Log(s)**
☐	**BSE/SRM Control**	☐	**Owner Information**

Square Footage and Area Location		
Please indicate square footage in each area	**Square Feet**	**Location**
Total Square Feet of the Facility		
Total Square Feet of Slaughter Area		
Total Square Feet of Processing Area		
Total Square Feet of Prep/Dishwashing Area		
Total Square Feet of Dry Storage		
Total Square Feet of Retail Areas		
Total Square Feet of Inedible Area		
Total Square Feet of Animal Holding Area		
Total Square Feet of Skinning Room		
Other:		
Other:		
Other:		

I. Meat Facility Slaughter and Processing Operations

A. What type of Slaughter operation will the facility be performing? (check all that apply)

☐ State Inspection ☐ Custom Exempt ☐ Mobile ☐ Wild Game

☐ On Farm Slaughter ☐ None ☐ Other _____

i. How many days per week of State Inspected slaughter are you requesting? Describe plan below: ☐1 Day ☐2 Days ☐3 Days ☐4Days ☐5 Days

ii. What animal species does your facility plan on slaughtering? In *Table 1*, please indicate the species and the anticipated number of head will be slaughtered per week.

Table 1: Species and Head Per Week		
Name of Animal Species		# Head Per Week
☐	**Beef**	
☐	**Pork**	
☐	**Lamb**	
☐	**Poultry**	
☐	**Goat**	
☐	**Buffalo** (Non-amenable voluntary inspection)	
☐	**Yak** (Non-amenable voluntary inspection)	
☐	**Other:**	
☐	**Other:**	
☐	**Other:**	
☐	**Other:**	

B. What type of processing operations will the facility be performing? (Check all that apply)
☐ State Inspected ☐ Custom Exempt ☐ Retail Exempt ☐ Wild Game

i. How many days per week of Stated Inspected processing are you requesting? Describe plan below: ☐1 Day ☐2 Days ☐3 Days ☐4Days ☐5 Days

ii. Will you be processing Raw, Not Ground Meat products?
☐ Yes ☐ No

iii. Will you be processing Raw Ground Meat products?
☐ Yes ☐ No

iv. Will your facility sell meat products retail onsite?
☐ Yes ☐ No

v. Will your facility be selling any Hotel, Restaurant, or Institution? ☐ Yes ☐ No
* Sales to HRI can only be raw product, and ***may not*** be cooked product. HRI cannot exceed 25% of retail sales.

vi. If your facility will be selling meat products retail onsite, please complete Table 2: Finish Schedule below.

Table 2: FINISH SCHEDULE						
Floors			Walls		Ceiling	
Material	Finish	Type of Base	Material	Finish	Material	Finish

C. Does your facility have a HACCP Plan for State Inspection? ☐ Yes ☐ No
If yes, please attach a copy of your facilities HACCP Plan. (HACCP plans are required for state inspection or retail exempt shelf stable products.)

i. Please name all employees in your facility that will be train in HACCP.

D. Will this facility do any outside catering? ☐ Yes ☐ No

E. Describe any other types of operations taking place at this facility?

II. Meat Facility Water and Sewer Supply

A. Select the type of water supply system that services the facility.

☐ Community/Public – Name of district/municipality:

Attach a letter from district/municipality confirming water supply.

☐ Private – Provide the most recent water sample test results.

Water must be sampled every six months. Results must be kept in establishment file. Please attach Approval from State Engineer's office

B. Select the type of sewage disposal system that services the establishment.

☐ Municipal/Public – Name of district/municipality:

If municipal/public, please include a letter confirming sewer hook-up.

☐ On-site Waste Water Treatment System – Indicate location on site plan and attach a copy of DEQ approval for the system.

III. Meat Facility Plumbing Plans

A. Complete Table 2 below for all meat facility related equipment or fixtures that require plumbing. Indicate how equipment or fixtures will be indirectly drained (e.g. floor sink or air gap), directly connected to the sewer, and/or what method of backflow prevention will be used, if applicable. If additional equipment is provided, please specify in the table below. Handwashing sinks in processing and slaughter area are required to be hands-free.

Table 2: Plumbing Equipment/Fixtures				
ID # on Plan	**Fixture or Equipment**	**Number**	**Indirect/Direct Drainage**	**Method of Backflow Prevention**
	Warewashing Facilities (3 comp sink)			
	Dish Machine			
	Garbage Disposals			
	Hands Free Handsinks			
	Handsinks			
	Food Preparation Sinks			
	Refrigeration Units			
	Ice Bins/Machines			
	Mop/Utility Sink			
	Chemical Dispensing Units			
	Hoses			
	Food Preparation Sinks			
	Other:			
	Other:			
	Other:			

Note: *Approved backflow protection must be supplied on all fixtures and equipment with submerged inlets. Vacuum breakers must be installed on water inlet lines for dishwashing machines, garbage disposals, and hose bibs. Continuous pressure backflow protection devices must be installed on water lines where a valve or shut off is located between the backflow device and the inlet to the fixture/equipment, such as hose reels. Indirect drainage is required for warewashing, food preparation sinks, ice bins/machines and beverage machines.*

B. Is a garbage disposal provided? ☐ Yes ☐ No

i. If yes, provide location:

C. Complete Table 3 and Table 4 for warewashing.

Will alternate equipment or methods be used in place of traditional drain boards? ☐ Yes ☐ No

If yes, indicate the methods that will be used:

Manual Warewashing– Include the size of each compartment (length x width x depth) of the warewashing sinks, soiled and clean drainboard lengths, and whether or not a pre-rinse spray hose will be installed for each warewashing area.

Table 3: Manual Warewashing Information				
ID # on Plans	**Length (inches) of Soiled Drainboard**	**Dimensions (inches) of Sink Compartments (LxWxD)**	**Length (inches) of Clean Drainboard**	**Pre-Rinse Sprayer Yes/No**

Note: Warewashing sinks must be large enough to accommodate the largest piece of equipment or utensils used.

Mechanical – Provide make and model numbers and attach specification sheets for each warewashing machine. Please indicate if the machine is heat or chemical sanitizing. Indicate soiled and clean drainboard length, whether or not a pre-rinse spray hose will be used, utensil soak sink dimension and water usage in gallons per hour (GPH).

Table 4: Mechanical Warewashing Information					
Make	**Model #**	**Heat/Chemical Sanitizing**	**Drainboard Length (inches)**	**Pre-Rinse Yes/No**	**Utensil Soak Sink Dimensions (inches)(LxWxH)**

D. Provide the following water heater information in Table 5. Please attach specification sheets.
   i. If more than one water heater is to be installed, please indicate which plumbing fixtures each heater or system will service.

Table 5: Water Heater			
Make	**Model #**	**Capacity (Gallons)**	**Water Temperature**

IV. Equipment and Storage Specifications

Submit equipment specification sheets, including make and model numbers. All equipment shall be made so that it is smooth, durable and cleanable.

A. Does your facility have a certified scale, certified by the Wyoming Department of Agriculture, Technical Services Division (307) 777-7324 ☐ Yes ☐ No

B. Provide the number of refrigeration/freezer units. Also provide capacities for refrigeration/freezer units in Table 6.

Table 6: Refrigeration/Freezer Capacities			
Type of Unit	**# of Units**	**Total Cubic Feet**	**Drain Type**
Walk-in Cooler			
Walk-in Drip Cooler			
Walk-in RTE Cooler			
Walk-in Freezer			
Reach-in Cooler			
Reach-in Freezer			
Blast Chiller			
Retail Display			
Other:			
Other:			

***All cold holding equipment must be commercial NSF certified equipment. Provide specification sheets for all condensation units being used in walk-in type coolers and freezer.**

i. Describe how condensation units for walk-in cooler and walk-in freezers are drained.

ii. Describe the types of shelving, if any, which will be placed in walk-in coolers and/or walk-in freezers.

iii. Will Processing or Fabrication rooms be cooled? If so, please describe.

C. Describe how the facility will be separating Raw and Ready-to-eat products.

***Facility will be required a separate Ready to Eat (RTE) cooler, if they choose to make RTE products.**

D. If your facility will be Slaughtering/Processing Wild Game, please describe how your facility will separate, identify, and lable wild game from Custom, or State products:

Will comingling of fat from custom to wild game occur? ☐ Yes ☐ No

If yes, describe how the facility will notify both parties:

E. Describe how foods, equipment, utensils, linens, and single-service articles will be stored and protected from contamination. (All foods shall be stored at least 6 inches off the floor.)

V. Ventilation Plans

A. Provide the location of each ventilation system, ventilation system type in the Table 7.

Table 7: Ventilation	
Location	**Type**
Kill Floor	
Processing Room	
Fabricating Room	
Smokehouse Area	
Cooked Product Area	
Inedible Cooler/Room	
Restroom	
Skinning Room	
Other:	

B. Provide the name and contact information of Fire Inspector. (Please attach approval letter from local Fire Inspector.)

Name:

Contact Information:

VI. Lighting Plans

A. Provide locations of lighting on plans. All lighting in slaughter areas, processing areas, smokehouse areas, dry storage areas, dishwashing areas, inside equipment, and above areas where open foods are held or displayed must be equipped with shatter proof bulbs or shields that will protect open food, carcasses, utensils, and single use items from broken glass if a bulb is broken. Different foot candles/lumens are required in different areas of your meat facility

i. Is the lighting in the Slaughter and Processing areas at least 50 Foot Candles?

☐ Yes ☐ No

ii. Is the lighting in the handwashing, warewashing, equipment and utensil storage areas at least 30 Foot Candles? ☐ Yes ☐ No

iii. Is the lighting in retail areas and inside reach-in coolers, walk-in coolers, walk-in freezers, and dry food storage at least 20 Foot Candles? ☐ Yes ☐ No

VII. Inedible Products and Waste Plans

A. Describe where the inedible room is located in the meat facility.

Is there sufficient ventilation in the inedible room to suppress odors and prevent insanitary conditions? Please describe ventilation below:

Are inedible containers leak-proof and properly labeled "INEDIBLE"? ☐ Yes ☐ No
(Lettering reading "INEDIBLE" must be no less than two inches high)

Describe who will remove inedible products from facility, frequency inedible products will be removed from facility, where inedible products will be disposed of, and what denaturant will be used?

How many dumpsters with lids and on a concrete pad or paved pad will be provided?

How often are dumpsters emptied?

Name of trash Disposal Company:

VIII. Outside Openings

A. Describe how facility is protecting outside openings from pest and rodent entry.

B. Describe the facilities Pest Control Plans

IX. Restrooms

A. How many restrooms will be in the facility?

B. Where are restrooms located in the facility?

C. Are restroom facilities complete with self-closing doors and vented to the outside?

☐ Yes ☐ No

X. Labeling

All labels that will be used for operations are required to be approved by this Department.

A. Describe how the facility will label safe handling information on packaging:

B. Will the facility be donating meat products? ☐ Yes ☐ No

If yes, describe how the facility will be labeling donated product:

C. Describe how the facility will be labeling custom not for sale products:

XI. Inspector Facilities

A. Do you have a Desk Area and a lockable file cabinet available for Inspector? If yes, identify on floor plan.

XII. Meat Processing Facilities

A. Will the processing facility have railing to transport carcasses? ☐Yes ☐ No

If yes, please complete Table 1 below. Please note, that to prevent contamination of carcasses, rails should be arranged to provide enough room for carcasses to move without touching equipment, walls, columns, other fixed parts of the building, and other carcasses.

Table 1: Railing		
Area	**Location**	**Rail Height (in feet)**
Drip Cooler 1		
Drip Cooler 2		
Processing Room 1		
Processing Room 2		
Drop Rail:		
Other:		

B. Will the processing facility have any hoists? ☐ Yes ☐ No

If yes, please complete Table 2.

Table 2: Hoist(s)		
Location	**Height**	**Capacity (in pounds)**

C. Describe cleaning and sanitizing procedures, location and frequency for troll hooks and gamble hooks used for operations.

D. Floors, walls, and ceilings in processing areas, walk-in cooler/freezers, should be constructed so that they are rigid, durable, non-toxic, non-corrosive, and impervious to moisture, should be a light solid color, and should be smooth or textured with an easily cleanable open pattern. Please use the finish schedule in Table 3 below to indicate interior floors, walls and ceiling finishes for each area within the processing facility.

Table 3: Finish Schedule				
Room Name	**Floors**	**Coving**	**Walls**	**Ceilings**
Kill Floor (Example)	*Quarry Tile*	*Sealed Cement*	*Fiberglass Reinforced Plastic (FRP)*	*Paneling*

*** Provide a specification sheet for all floor, walls, and ceiling material**

XIII. Processing Equipment

A. Any commercial processing equipment that is intended for use in an inspected facility shall meet the requirements of the Wyoming Food Safety Rule, Chapter 4 and Chapter 6, 9 CFR 317.20-21 and CFR 416 – 416.6. Please use Table 4: Equipment Schedule to indicate equipment to be installed in facility.

Table 4:Equipment Schedule				
Equipment Installation List				
ID # on Plan	Equipment	Make/Model	New (N) / Used (U)	Plumbing Required Y/N

***Please provide specification sheets for all equipment. For used provide a photograph of equipment.**

B. Provide information regarding how the facility will be packaging products. Packaging materials, and non-meat ingredients must have letters of guarantee on file.

C. Please list all chemicals that will be used in the facility.

XIV. Processing Facility Processes

A. Please describe your facilities plan for BSE/SRM removal at fabrication below:

B. List all products the facility plans on making and how they will be made below in Table 5:

Table 5: Meat Product Schedule		
Product	**Cooked/Cured**	**Description**

C. Describe where your facility will be mixing spices for raw and or cooked products:
Note: A properly supplied handwashing sink will be required in spice mixing area/room.

XV. MEAT HACCP TRAINING

A. Please list all employees who will be or are Meat HACCP trained:

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CHAPTER 1

PURPOSE, VARIANCES, DEFINITIONS, DEMONSTRATION OF KNOWLEDGE, AND HEALTH STATUS

Section 1. Authority. Pursuant to the authority vested in the director of the Wyoming department of agriculture by virtue of W.S. 35-7-120, 35-7-123 (a) (iii), and 35-7-127, together with the department of health and the governor's food safety council established pursuant to W.S. 35-7-127, the following rules are hereby promulgated.

Section 2. Wyoming Food Safety Rule.

(a) These provisions shall be known as the Wyoming Food Safety Rule, hereinafter referred to as this Rule.

Section 3. Statement of Purpose.

(a) The purpose of this Rule is to safeguard public health and assure consumers that food is safe, unadulterated, and honestly presented.

(b) This Rule establishes definitions; sets standards for management and personnel, food operations, equipment and facilities; and provides for establishment or processing plant plan review, license issuance, inspection, employee restriction, and license suspension.

Section 4. Public Health Protection.

(a) The regulatory authority shall apply this Rule to promote its underlying purpose of safeguarding the public health and assuring that food is safe, unadulterated, and honestly presented when offered to the consumer.

(b) In enforcing the provisions of this Rule, the regulatory authority shall assess existing facilities or equipment that were in use before the effective date of this Rule based on the following considerations:

(i) Whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition;

(ii) Whether food-contact surfaces comply with Chapter 6, Section 13;

(iii) Whether the capacities of cooling, heating, and holding equipment

are sufficient to comply with Chapter 3, Section 30; and

(iv) The existence of a documented agreement with the license holder that the facilities or equipment will be replaced as specified under Chapter 2, Section 12 (a)(vii), or upgraded or replaced as specified under Chapter 2, Section 12 (a)(vii)(A).

Section 5. Variances of Modifications and Waivers.

(a) The Wyoming department of agriculture may grant a variance by modifying or waiving the requirements of this Rule if in the opinion of the Wyoming department of agriculture a health hazard or nuisance will not result from the variance. If a variance is granted, the Wyoming department of agriculture shall retain the information specified under Chapter 1, Section 6, in its records for the establishment or processing plant.

Section 6. Documentation of Proposed Variance and Justification.

(a) Before a variance from a requirement of this Rule is approved, the information that shall be provided by the person requesting the variance and retained in the Wyoming department of agriculture's file on the establishment or processing plant must include:

(i) A statement of the proposed variance of the Rule requirement citing relevant Rule Section numbers;

(ii) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Rule Sections will be alternatively addressed by the proposal; and

(iii) A HACCP Plan if required as specified under Chapter 10, Section 1(a) that includes the information specified under Chapter 10, Section 2, as it is relevant to the variance requested.

Section 7. Variance Requirements.

(a) If the Wyoming department of agriculture grants a variance as specified in Chapter 1, Section 6, or a HACCP plan is otherwise required as specified under Chapter 10, Section 1, the license holder shall:

(i) Comply with the HACCP Plan and procedures that are submitted as specified under Chapter 10, Section 2, and approved as a basis for the modification or waiver; and

(ii) Maintain and provide to the Wyoming department of agriculture, upon request, records specified under Chapter 10, Section 2 (a) (iv) and (v), that demonstrate that the following are routinely employed:

(A) Procedures for monitoring critical control points;

(B) Monitoring of the critical control points;

(C) Verification of the effectiveness of an operation or process; and

(D) Necessary corrective actions if there is failure at a critical control point.

Section 8. Applicability and Terms Defined.

(a) The following terms are defined and apply in the interpretation and application of this Rule.

(i) "Accredited program."

(A) "Accredited program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

(B) "Accredited program" refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(C) "Accredited program" does not refer to training functions or educational programs.

(ii) "Additive."

(A) "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, §201(s) and 21 CFR 170.3 (e) 1 Food Additives.

(B) “Color additive” has the meaning stated in the Federal Food, Drug, and Cosmetic Act, §201 (t) and 21 CFR 70.3 (f) Color Additives.

(iii) "Administrative meeting" means an informal meeting conducted by the Wyoming department of agriculture for the purpose of facilitating a mutually agreed

upon plan of compliance for the license holder.

(iv) "Adulterated" has the meaning stated in the Federal Food, Drug and Cosmetic Act § 402 and 9 CFR 301.2 Definitions.

(v) "Animals" means but is not limited to livestock as defined in 9 CFR 301 Definitions, poultry as defined in 9 CFR 381.1 Definitions, or exotic animals as defined in 9 CFR 352.1 Definitions, and fish.

(vi) "Approved" means acceptable to the regulatory authority based on determination of conformity with principles, practices, and generally recognized standards that protect public health.

(vii) "Approved source" when used in reference to a bottled water plant's water product or water used in the plant's operations, means the source(s) of the water whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality in accordance with the applicable laws and regulations of the State of Wyoming. The presence in the plant of current certificates or modifications of approval from the State Engineer shall constitute approval of the source in the case of non-municipal water supplies.

(viii) "Approved water source" means any public water source or private well that has been routinely sampled and verified to not have contaminants in excess of the legal maximum contaminant levels as outlined in the primary Environmental Protection Agency (EPA) water quality standards.

(ix) "Artesian water" means bottled water from a well tapping an aquifer in which the water level will stand above the bottom of the confining bed of the aquifer and in which the hydraulic pressure of the water in the aquifer is greater than the force of gravity. "Artesian well water" shall meet the requirements of "natural water."

(x) “Asymptomatic.”

(A) "Asymptomatic" means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice.

(B) "Asymptomatic" includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

(xi) "a_w" means water activity which is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w.

(xii) "Balut" means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

(xiii) "Bed and breakfast facility" means a private home which is used to provide temporary accommodations for a charge to the public with not more than four (4) lodging units or not more than a daily average of eight (8) persons per night during any thirty (30) day period and in which no more than two (2) family style meals are provided per twenty four (24) hour period.

(xiv) "Beverage" means a liquid for drinking, including water.

(xv) "Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(xvi) “Bulk water hauler” means a person who hauls water in a bulk tank or in containers of 250 gallons or more for human consumption or for use in a licensed establishment or processing plant.

(A) A person hauling bulk water for private use in their own home is exempt from the bulk water requirements in this Rule.

(xvii) "Carcass" means all or any part of a slaughtered animal, including viscera, which is capable of being used for human consumption.

(xviii) “Casing” means a tubular container for sausage products made of either natural or artificial (synthetic) material.

(xix) "Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

(xx) "CFR" means Code of Federal Regulations. Citations in this Rule to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR 178.1010 refers to Title 21, Part 178, Section 1010.

(xxi) "CIP."

(A) "CIP" means cleaned in place by circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine.

(B) "CIP" does not include the cleaning of equipment such as

band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

(xxii) "Code of Federal Regulations" means the compilation of the general and permanent regulations published in the Federal Register by the executive departments and agencies of the federal government which:

(A) Is published annually by the U.S. Government Printing Office; and

(B) Contains FDA regulations in 21 CFR, USDA regulations in 7 CFR and 9 CFR, EPA regulations in 40 CFR, and Wildlife and Fisheries regulations in 50 CFR.

(xxiii) "Comb honey" means honey contained in the cells of the comb in which it is produced.

(xxiv) “Commingle” means:

(A) To combine shellstock harvested on different days or from different growing areas as identified on the tag or label, or

(B) To combine shucked shellfish from containers with different container codes or different shucking dates.

(xxv) "Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing.

(A) "Comminuted" includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage; and a mixture of two (2) or more types of meat that have been reduced in size and combined, such as sausages made from two (2) or more meats.

(xxvi) "Conditional employee" means a potential food employee to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

(xxvii) "Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness.

(xxviii)"Consumer" means a person who is a member of the public, who takes possession of food, who is not functioning in the capacity of an operator of an

establishment or processing plant, or who does not offer the food for resale.

(xxix) "Contaminant" means any physical, chemical, biological or radiological substance or matter in water.

(xxx) "Contract veterinarian" means a graduate of a school of veterinary medicine accredited by the American Veterinary Medical Association who provides services for the department under contract, and who is licensed to practice veterinary medicine in the state of Wyoming."

(xxxi) "Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of use environment.

(xxxii) “Counter-mounted equipment” means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

(xxxiii) “Cottage food business” means a business which produces not potentially hazardous food for sale at farmers’ markets, roadside stands, private homes, or functions utilizing the home style equipment in the kitchen of a private home.

(xxxiv)"Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk

(xxxv) "Critical item."

(A) "Critical item or critical violation" means a provision of this Rule, that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard.

(xxxvi)"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

(xxxvii)"Cured" means meat to which specific non-meat ingredients have been incorporated by dry addition or use of aqueous solutions to affect preservation, safety, flavor, and/or color. The non-meat ingredients must include salt (sodium chloride), and most often include sodium nitrite/nitrate. In addition, sugar (sucrose) or other sweetening agents are frequently used.

(xxxviii)"Custom carcass or meat" means carcasses, meat, meat food products or meat by-products which were slaughtered, dressed or otherwise processed by license holders.

(xxxix) "Department" means the Wyoming department of agriculture.

(xl) "Director" means the director of the Wyoming department of agriculture or his duly authorized representative.

(xli) "Disinfectant" means any oxidant, including but not limited to, chlorine, chlorine dioxide, chloramines and ozone added to water in any part of the treatment or distribution process that is intended to kill or inactivate pathogenic microorganisms.

(xlii) "Distilled water" means bottled water which has been produced by a process of distillation and meets the definition of purified water in the 21st Edition of the United States Pharmacopeia.

(xliii) "Distressed merchandise" means any food:

(A) Which has had the label lost;

(B) Which has been subjected to possible damage due to accident, fire, flood, adverse weather, or any other similar cause; or

(C) Which may have been rendered unsafe or unsuitable for human or animal consumption or use.

(xliv) "Drinking water."

(A) "Drinking water" means water that meets 40 CFR 141 National Primary Drinking Water Regulations.

(B) "Drinking water" is traditionally known as "potable water."

(C) "Drinking water" includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

(xlv) "Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single-service items.

(xlvi) "Easily cleanable."

(A) "Easily cleanable" means a characteristic of a surface that:

(I) Allows effective removal of soil by normal cleaning methods;

(II) Is dependent on the material, design, construction, and installation of the surface; and

(III) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

(B) "Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified under Subparagraph (A) of this definition, to different situations in which varying degrees of cleanability are required such as:

(I) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or

(II) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

(xlvii) "Easily movable" means:

(A) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and

(B) Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

(xlviii) "Edible" means intended for use as human food.

(xlix) “Egg”

(A) “Egg” means the shell egg of avian species such as chicken, turkey, duck, goose, guinea, quail or ratite.

(B) "Egg" does not include:

(I) A balut;

(II) The egg of reptile species such as alligator; or

(III) An egg product.

(l) “Egg Product.”

(A) "Egg Product" means all, or a portion of, the contents found inside eggs separated from the shell and pasteurized in a food processing plant, with or without added ingredients, intended for human consumption, such as dried, frozen or liquid eggs.

(B) “Egg Product" does not include food which contains eggs only in a relatively small proportion such as cake mixes.

(li) "Employee" means the license holder, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in an establishment or processing plant.

(lii) "Enterohemorrhagic *Escherichia coli*" (EHEC) means *E. coli* which cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. The term is typically used in association with *E. coli* that have the capacity to produce Shiga toxins and to cause attaching and effacing lesions in the intestine. EHEC is a subset of STEC, whose members produce additional virulence factors. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Examples of serotypes of EHEC include: *E. coli* O157:H7; *E. coli* O157:NM; *E. coli* O26:H11; *E. coli* O145:NM; *E. coli* O103:H2; or *E. coli* O111:NM. *Also see* shiga toxin-producing *e. coli.*

(liii) "EPA" means the U.S. Environmental Protection Agency.

(liv) "Equipment."

(A) "Equipment" means an article that is used in the operation of a food establishment such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine.

(B) "Equipment" does not include items used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

(lv) "Establishment."

(A) "Establishment" means and includes any place or any area of any establishment in which food, drugs, devices and cosmetics are displayed for sale, manufactured, processed, packed, held or stored:

(I) Including but not limited to, a restaurant; retail store; meat slaughter or processing plant, dairy production and processing; bed and

breakfast; bulk water hauler; satellite, group day care center or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and

(II) That relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(B) "Establishment" includes:

(I) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and

(II) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food.

(C) "Establishment" does not include:

(I) A kitchen in a private home if only food that is not potentially hazardous is prepared for sale or use at farmers' markets, roadside stands, private homes or functions.

(II) An area where food that is prepared as specified in Subparagraph (C) (I) of this definition, is sold;

(III) A kitchen in a private home, such as a small family day-care provider;

(IV) A private home that receives catered or home-delivered food;

(V) A home kitchen where food is prepared and stored for family consumption; or

(VI) Any other place equipped for the preparation, consumption and storage of food on the premise by employees or nonpaying guests.

(lvi) "Establishment number" means an official number assigned by the director to each establishment and included on the inspection legend and label to identify all inspected and passed carcasses, meat, meat food products and meat by-products handled in that establishment.

(lvii) “Exclude” means to prevent a person from working as a food employee or entering an establishment or processing plant as a food employee.

(lviii) "Exotic animal" means any reindeer, elk, deer, antelope, water buffalo or bison.

(lix) "Extracted honey" means honey that has been separated from the comb by centrifugal force, gravity, straining, or by other means.

(lx) “Farmers market” means a common facility or area where several vendors may gather on a regular, recurring basis to sell a variety of fresh fruits and vegetables, locally grown farm products and other items directly to consumers.

(lxi) “FDA” means the U.S. Food and Drug Administration.

(lxii) "Family style meals" means a meal prepared in a bed and breakfast facility or ranch recreation facility and served in the same facility around a common table(s). At no time would a menu or a preselected list of foods be available, and all foods not consumed, which were of a potentially hazardous nature, would be discarded following the meal.

(lxiii) "Federal inspection" means meat and poultry inspection services conducted or approved by the meat inspection division and the poultry inspection division of the United States Department of Agriculture.

(lxiv) "Federal Meat Inspection Act" means the act of congress approved March 4, 1907, and extended and the imported meat provisions of subsections 306 (b) and (c) of the Tariff Act of 1930 and 9 U.S.C. 1306 (b) and (c).

(lxv) "Federal Poultry Products Inspection Act" means the act of congress approved August 28, 1957, by the Wholesome Poultry Products Act, 82 Stat. 791; 21 U.S.C. 451.

(lxvi) "Fish."

(A) "Fish" means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

(B) "Fish" includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

(lxvii) "Fluoridated water" means bottled water containing naturally occurring or added fluoride. The label shall specify whether the fluoride is naturally

occurring or added. Any water which meets the definition of this paragraph shall contain not less than 0.7 and not more than 1.4 mg/l fluoride ions and otherwise comply with the Food and Drug Administration quality standards set forth in 21 CFR 165.110 Bottled Water.

(lxviii) "Food" means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(lxix) "Foodborne disease outbreak" means the occurrence of two (2) or more cases of a similar illness resulting from the ingestion of a common food.

(lxx) "Food-contact surface" means:

(A) A surface of equipment or a utensil with which food normally comes into contact; or

(B) A surface of equipment or a utensil from which food may drain, drip, or splash:

(I) Into a food; or

(II) Onto a surface normally in contact with food.

(lxxi) "Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

(lxxii) “Function” means any official ceremony or organized social occasion.

(lxxiii) "Game animals" means any big game animal, elk, deer, mountain sheep, wild goat, antelope, moose or bear.

(lxxiv) "General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175 Pesticides classified for restricted use.

(lxxv) "Grade A standards" means the requirements of the United States Public Health Service/FDA Grade A Pasteurized Milk Ordinance and Grade A Condensed and Dry Milk Ordinance with which certain fluid and dry milk and milk products must comply.

(lxxvi) "HACCP plan" means a written document that delineates the Formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(lxxvii) “Handwashing Sink.”

(A) "Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a plumbing fixture especially placed for use in personal hygiene and designed for the washing of the hands.

(B) "Handwashing sink" includes an automatic handwashing facility.

(lxxviii) "Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

(lxxix) "Health officer" means the person appointed by the director of the department of health pursuant to W.S. 9-2-101(f) and 9-2-103.

(lxxx) "Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a nurse practitioner, physician assistant, or similar medical professional.

(lxxxi) "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

(lxxxii) "Highly susceptible population" means a group that is composed of persons who are more likely than other groups of persons in the general population to experience foodborne disease because they are:

(A) Immunocompromised, older adults, or preschool age children; and

(B) Obtain food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

(lxxxiii) "Honey" means a food product which is the nectar and saccharin exudation of plants gathered, modified, and stored in the comb by honey bees; is levorotatory; and contains not more than twenty-five percent (25%) of water, not more than twenty-five hundredths percent (.25%) of ash, nor more than eight percent (8%) sucrose.

(lxxxiv) "Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(A) The number of potential injuries; and

(B) The nature, severity, and duration of the anticipated injury.

(lxxxv) "Injected" means manipulating ~~a~~ meat to which a solution has been introduced into its interior by processes that are referred to as "injecting," “pump marinating” or "stitch pumping.”

(lxxxvi) "Juice."

(A) "Juice," when used in the context of food safety, means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

(B) "Juice" does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

(lxxxvii) "Kitchenware" means food preparation and storage utensils.

(lxxxviii) "Law" means applicable local, state, and federal statutes, rules, regulations, and ordinances.

(lxxxix) "License" means the document issued by the regulatory authority that authorizes a person to operate an establishment or a processing plant.

(xc) "License holder" means the entity that:

(A) Is legally responsible for the operation of the establishment or processing plant such as the owner, the owner's agent, or other person; and

(B) Possesses a valid license to operate an establishment or processing plant.

(xci) "Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

(xcii) "Lodging unit" means a room with one (1) or more beds, bunks or other facilities for sleeping purposes for an unspecified number of persons.

(xciii) “Major Food Allergen.”

(A) "Major food allergen" means:

(I) Milk, egg, fish (such as bass, flounder, cod, and

including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(II) A food ingredient that contains protein derived from a food, as specified in Subparagraph (A)(I) of this definition.

(B) "Major food allergen" does not include:

(I) Any highly refined oil derived from a food specified in Subparagraph (A)(I) of this definition and any ingredient derived from such highly refined oil; or

(II) Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282).

(xciv) "Manufactured" means meat which has been processed by curing, smoking, canning, cooking, freezing, dehydration, production of intermediate moisture products, and/or the use of certain additives, chemicals, and enzymes into a product different from the starting raw material. This definition shall not include simple grinding, cutting, or mixing.

(xcv) "Manufacturing Milk" means milk for manufacturing purposes produced for processing and manufacturing into products for human consumption but not subject to Grade A or comparable requirements.

(xcvi) "Meat" means the edible part of the muscle of animals, which is skeletal or which is found in the tongue, in the diaphragm, in the heart or in the esophagus, with or without the accompanying or overlying fat, and the portions of bone, skin, sinew, nerve and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing; it does not include the muscle found in the lips, snout or ears.

(A) This definition shall be limited to livestock as defined in 9 CFR 301.2 Definitions.

(xcvii) "Meat by-product" means any edible part of an animal other than meat or meat food products.

(xcviii) "Meat food product" means any article of food for human consumption or any article which enters into the composition of food for human consumption, which is derived or prepared in whole or in part from any portion of any animal, except organotherapeutic substances, meat juices, meat extract and the like which are only for medicinal purposes and are advertised only to the medical profession; any edible part of the carcass which has been manufactured, cured, smoked, processed or

otherwise treated shall be considered a meat food product.

(xcix) “Mechanically Tenderized.”

(A) “Mechanically tenderized” means manipulating meat with deep penetration by processes which may be referred to as “blade tenderizing,” “jaccarding,” “pinning,” “needling,” or using blades, pins, needles or any mechanical device.

(B) “Mechanically tenderized” does not include processes by which solutions are injected into meat.

(c) "mg/l" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

(ci) "Milk grader or milk hauler" means any person who samples, approves or rejects raw milk for utilization in milk products.

(cii) "Milk tester" means any person who tests samples of milk taken by a milk grader for the purpose of determining compliance with this Rule, the United States Public Health Service/FDA Grade A Pasteurized Milk Ordinance, or for payment purposes.

(ciii) "Mineral water" means bottled water that contains not less than 500 parts per million mineral solids. "Mineral water" shall meet the requirements of "Natural water."

(civ) "Misbranded" has the meaning stated in the Federal Food, Drug and Cosmetic Act, 21 USC 343 or 9 CFR 301.2 Definition.

(cv) "Mobile establishment" means an establishment designed to be readily movable such as a vehicle-mounted unit or a pushcart.

(cvi) "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

(cvii) "Natural water" means bottled spring, artesian well, or well water which is not derived from a public system and which is unmodified by blending with water from another source or by mineral addition or deletion, except as it relates to ozonation or equivalent disinfection and filtration.

(cviii) “Non-continuous cooking.”

(A) “Non-continuous cooking” means the cooking of food in a

food establishment or processing plant using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service.

(B) “Non-continuous cooking” does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

(cix) "Non-salvageable merchandise" means "distressed merchandise," which cannot be safely or practically reconditioned.

(cx) “Not potentially hazardous food” means any food which does not require time or temperature control for safety to limit pathogenic microorganism growth or toxin formation. The natural pH or the final pH of acidified food must be 4.6 or less.

(cxi) "Official establishment" means any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulatory authority and this Rule.

(cxii) "Official inspection legend" means any symbol prescribed by the director showing that an article was inspected and passed in accordance with this Rule.

(cxiii) "Official inspection mark" means any symbol prescribed by the director for the purpose of identifying the inspection status of any article so inspected.

(cxiv) "Packaged."

(A) "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in an establishment or processing plant.

(B) "Packaged" does not include a wrapper, carry-out box, or other nondurable container used to contain food with the purpose of facilitating food protection during service and receipt of the food by the consumer.

(cxv) "Perishable" means there exists a significant risk of spoilage or deterioration when a product has not been properly refrigerated or handled.

(cxvi) "Person" means an individual, partnership, a corporation, association, other legal entity, government, or governmental subdivision or agency.

(cxvii) "Person in charge" means the individual present at an establishment or processing plant who is responsible for the operation at the time of inspection.

(cxviii) "Personal care items."

(A) "Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance.

(B) "Personal care items" include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

(cxix) "pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between zero (0) and seven (7) indicate acidity and values between seven (7) and fourteen (14) indicate alkalinity. The value for pure distilled water is seven (7), which is considered neutral.

(cxx) "Physical facilities" means the structure and interior surfaces of an establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

(cxxi) "Plumbing fixture" means a receptacle or device that:

(A) Is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or

(B) Discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

(cxxii) "Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

(cxxiii)"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in the following four (4) categories:

(A) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(B) Pesticides except sanitizers, which include substances such as insecticides and rodenticides;

(C) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(D) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

(cxxiv) “Potentially Hazardous Food (Time/Temperature Control for Safety Food).”

(A) "Potentially hazardous food (time/temperature control for safety food)" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(B) "Potentially hazardous food (time/temperature control for safety food)" includes:

(I) An animal food that is raw or heat-treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way to be unable to support pathogenic microorganism growth or toxin formation; and

(II) Except as specified in Subparagraph (C)(IV) of this definition, a food that because of the interaction of its Aw and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of pH and aw for control of spores in food heat treated to destroy vegetative cells and subsequently packaged

Aw values	pH		
	4.6 or less	> 4.6 - 5.6	> 5.6
<0.92	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food
> 0.92- 95	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
> 0.95	non-PHF/non-TCS food	PA	PA

* PHF means potentially hazardous food
** TCS food means time/temperature control for safety food
*** PA means Product Assessment required

Table B. Interaction of pH and Aw for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged				
Aw values	pH			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	non-PHF*/ non-TCS food**	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food
0.88 – 0.90	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA***
> 0.90–0.92	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA	PA
> 0.92	non-PHF/ non-TCS food	PA	PA	PA
* PHF means Potentially Hazardous Food ** TCS food means time/temperature control for safety food *** PA means Product Assessment required				

(C) "Potentially hazardous food (time/temperature control for safety food)" does not include:

(I) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;

(II) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;

(III) A food that because of its pH or Aw value, or interaction of Aw and pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;

(IV) A food that is designated as Product Assessment Required (PA) Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(1.) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,

(2.) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or

(3.) A combination of intrinsic and extrinsic factors; or

(V) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (C)(I) - (C)(IV) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

(cxxv) “Poultry."

(A) "Poultry" means:

(I) Any domesticated bird (chickens, turkeys, ducks, geese, guineas or ratites), whether live or dead, as defined in 9 CFR 381 Poultry Products Inspection Regulations; and

(II) Any migratory waterfowl, game bird, such as pheasant, partridge, quail, grouse, guinea, pigeon, or squab, whether live or dead, as defined in 9 CFR 362 Voluntary Poultry Inspection Regulations.

(cxxvi) "Premises" means:

(A) The physical facility, its contents, and the contiguous land or property under the control of the license holder; or

(B) The physical facility, its contents, and the land or property not described under Subparagraph (A) of this definition, if its facilities and contents are under the control of the license holder and may impact the establishment or processing plant personnel, facilities, or operations, if an establishment or processing plant is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

(cxxvii) "Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.

(cxxviii) "Processed" as applied to meat products means fresh meat which has been altered to affect preservation and/or manufacture of meat products, except for simple grinding, cutting, or mixing. This includes curing, smoking, canning, cooking, freezing, dehydration, production of intermediate moisture products, and the use of

certain additives, chemicals, and enzymes. Processed does not include otherwise unprocessed meats that are sold in a frozen state.

(cxxix) "Processing plant."

(A) "Processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption, and provides food for sale or distribution to other business entities such as processing plants or establishments, and may provide food directly to a consumer.

(B) "Processing plant" does not include an establishment as defined under Chapter 1, Section 8 (lvi).

(cxxx) "Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

(cxxxi) "Purified water" means bottled water produced by distillation, deionization, reverse osmosis, or other suitable process and meets the requirements of purified water in the 21st Edition of the United States Pharmacopeia. Water which meets the definition of this paragraph, and is vaporized, then condensed, may be labeled "distilled water."

(cxxxii) "Ranch recreation facility" means a ranch/farm facility containing or having under use agreement one hundred sixty (160) acres or more which may for a charge to the public provide activities for not more than a daily average of eight (8) persons in any given thirty (30) day period or may include sleeping facilities in not more than four (4) sleeping units along with accompanying family style meals. Meals and lodging shall be considered an adjunct to the activities which take place on the ranch and are not available to non-registered guests. This definition does not apply to a dude ranch.

(cxxxiii) "Ratite" means a group of flightless birds including ostriches, cassowaries, kiwis, emus, etc., having undeveloped wings and a breastbone without a keel.

(cxxxiv) "Ready-to-eat food."

(A) "Ready-to-eat food" means food that:

(I) Is in a form that is edible without additional preparation to achieve food safety, as specified under Chapter 3, Section 41(a)-(c), Section 42, or Section 34; or

(II) Is a raw or partially cooked animal food and the consumer is advised as specified under Chapter 3, Section 41(d)(i) and (ii); or

(III) Is prepared in accordance with a variance that is granted as specified under Chapter 3, Section 41(d)(i) and (iii); and

(IV) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

(B) "Ready-to-eat food" includes:

(I) Raw animal food that is cooked as specified under Chapter 3, Sections 41 and 42, or frozen as specified under Chapter 3, Section 34;

(II) Raw fruits and vegetables that are washed as specified under Chapter 3, Section 40;

(III) Fruits and vegetables that are cooked for hot holding, as specified under Chapter 3, Section 43;

(IV) All potentially hazardous food that is cooked to the temperature and time required for the specific food under Chapter 3, Section 41, 42, 43, and cooled as specified in Chapter 3, Section 31;

(V) Plant food for which further washing, cooking, or other processing is not required for food safety and from which rinds, peels, husks, or shells, if naturally present, are removed;

(VI) Substances derived from plants such as spices, seasonings, and sugar;

(VII) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;

(VIII) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and parma ham; and dried meat and poultry products, such as jerky or beef sticks; and

(IX) Foods manufactured according to 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

(cxxxv) "Reconditioning" means any appropriate process or procedure by which distressed merchandise can be brought into compliance with the standards of the regulatory authority for consumption or use by the public.

(cxxxvi) "Reconstituted" means dehydrated food products

recombined with water or other liquids.

(cxxxvii) "Reduced oxygen packaging."

(A) "Reduced oxygen packaging" means:

(I) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding 21% oxygen atmosphere; and

(II) A process as specified in Subparagraph (A)(I) of this definition that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form.

(B) "Reduced oxygen packaging" includes:

(I) Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

(II) Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

(III) Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material;

(IV) Cook chill packaging, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

(V) Sous vide packaging, in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(cxxxviii) "Refuse" means solid waste not carried by water through

the sewage system.

(cxxxix) "Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the establishment or processing plant.

(cxl) “Restrict” means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens; and unwrapped single-service or single-use articles.

(cxli) “Restricted egg” means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590 Inspection of Eggs and Egg Products (Egg Products Inspection Act).

(cxlii) "Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

(cxliii) "Re-service" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.

(cxliv) “Risk” means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

(cxlv) "Safe materials" means:

(A) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food;

(B) An additive that is used as specified in Section 409 of the Federal Food, Drug, and Cosmetic Act; or

(C) Other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

(cxlvi) "Salvage distributor" means a person who engages in the business of selling, distribution or otherwise trafficking in any distressed or salvaged merchandise.

(cxlvii)"Salvage handler" means a person who engages in the business of handling distressed merchandise at the scene of an accident, fire, flood or other disaster, with or without taking ownership of the distressed merchandise.

(cxlviii) "Salvage processing plant" means an establishment primarily engaged in the business of reconditioning or by other means salvaging distressed merchandise and which sells or distributes salvaged merchandise for human or animal consumption or use.

(cxlix) "Salvageable merchandise" means any distressed merchandise which can be reconditioned to the satisfaction of the regulatory authority.

(cl) "Salvaged merchandise" means distressed merchandise which has been reconditioned.

(cli) "Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five (5) logs, which is equal to a ninety nine and nine hundred ninety nine thousandths percent (99.999%) reduction, of representative disease microorganisms of public health importance.

(clii) "Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

(cliii) "Service animal" means any dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability.

(A) Other species of animals, whether wild or domestic, trained or untrained, are not service animals for the purposes of this definition.

(B) The work or tasks performed by a service animal must be directly related to the handler's disability.

(cliv) "Servicing area" means an operating base location to which a mobile establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

(clv) "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

(clvi) "Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

(clvii) "Shellstock" means raw, in-shell molluscan shellfish.

(clviii) “Shiga toxin-producing *Escherichia coli*” means any *E. coli* capable of producing Shiga toxins (also called verocytotoxins or “Shiga-like” toxins). Examples of serotypes of STEC include both O157 and non-O157 *E. coli*. *Also see* Enterohemorrhagic *Escherichia coli.*

(clix) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

(clx) "Single-service article" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

(clxi) "Single-use articles."

(A) "Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded.

(B) "Single-use articles" include items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number ten (10) cans which do not meet the materials, durability, strength, and cleanability specifications under Chapter 6, Sections 1, 13 and 16, for multi-use utensils.

(clxii) "Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -10^{o}F (-23^{o}C) to 25^{o}F (-4^{o} C) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.

(clxiii) "Slaughterhouse" shall include all buildings, structures, and facilities used in the slaughtering or dressing of animals for human consumption.

(clxiv) "Smoked" means meat to which smoke or smoke flavorings have been applied/added for the purpose of preservation, color, flavor, and/or aroma.

(clxv) "Smooth" means:

(A) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of one hundred (100) grit number three (3) stainless steel;

(B) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(C) A floor, wall, or ceiling having an even or level surface

with no roughness or projections that renders it difficult to clean.

(clxvi) "Spring water" means water derived from an underground formation from which water flows naturally to the surface of the earth. "Spring water" shall meet the requirements of "natural water."

(clxvii)"Table-mounted equipment" means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

(clxviii) "Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

(clxix) "Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

(clxx) "Temporary establishment" means an establishment that operates for a period of no more than fourteen (14) consecutive days in conjunction with a single event or celebration.

(clxxi) "Temporary Sampling Establishment" means an establishment that operates for a period of no more than fourteen (14) individual days within three (3) consecutive months in conjunction with farmers' markets or other events held at a single location where:

(A) Only free samples of products sold by vendors who hold a food (distributors/processors) license or by agricultural producers may be provided to the public;

(B) Free samples and associated products sold under the food (distributors/processors) license shall meet all requirements of the Wyoming Food Safety Rule during processing;

(C) Temporary establishment licensing requirements and fees apply; and

(D) Whole intact product is exempt from the temporary sampling establishment license.

(clxxii) "Unwholesome" means any animal, carcass, meat, meat food product or meat by product which:

(A) Is unsound, injurious to health, contains any biological residue not permitted under these rules, or is otherwise unfit for human consumption;

(B) Consists in whole or in part of any filthy, putrid or decomposed substance;

(C) Was processed, prepared, packed or held under insanitary conditions so that the same may have become contaminated or may have become injurious to health;

(D) Was produced in whole or in part from animals which died other than by slaughter.

(clxxiii) "USDA" means the U.S. Department of Agriculture.

(clxxiv) "Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multi-use, single-service, or single-use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices; and probe-type price or identification tags used in contact with food.

(clxxv) "Variance" means a written document issued by the Wyoming Department of Agriculture that authorizes a modification or waiver of one or more requirements of this Rule if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

(clxxvi) "Vehicle" means any truck, car, bus, or other means by which distressed, salvageable or salvaged merchandise is transported from one location to another.

(clxxvii) "Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

(clxxviii) "Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage areas and areas on the premises that are used to service and maintain the vending machines.

(clxxix) "Warewashing" means the cleaning and sanitizing of food-contact surfaces of equipment and utensils.

(clxxx) "Water hauler" means any person engaged in the distribution of bulk quantities of water by truck or other type of vehicle or conveyance, for sale for human consumption.

(clxxxi) "Well water" means bottled water from a hole bored,

drilled, or otherwise constructed in the ground, which taps the water of an aquifer. "Well water" shall meet the requirements of "natural water."

(clxxxii) "Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

(clxxxiii) "Wholesome" means sound, healthful, clean and otherwise fit for human consumption.

(clxxxiv) "Wyoming condemned," or abbreviation thereof, means the animal so marked has been inspected and found to be in a dying condition, or to be affected with any other condition or disease that would require condemnation of its carcass.

(clxxxv) "Wyoming inspected and condemned," or abbreviation thereof, means that the carcass, meat, meat food product or meat by-product, so marked or so identified, is unwholesome or adulterated and shall be disposed of in the manner prescribed by the director.

(clxxxvi) "Wyoming inspected and passed," or abbreviation thereof, means that the carcass, meat, meat food product, or meat by-product, so marked or so identified, was at the time it was so marked or so identified found to be wholesome.

(clxxxvii) "Wyoming retained" means that the carcass, meat, meat food product so identified is held for further examination by the director or contract veterinarian to determine its disposal.

(clxxxviii) "Wyoming suspect" means that an animal so marked and identified is suspected of being affected with a disease or condition which may require its condemnation, in whole or in part, when slaughtered, and is subject to further examination by the director or a contract veterinarian to determine its disposal.

Section 9. Person in Charge Requirement.

(a) The license holder shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the establishment or processing plant during all hours of operation.

Section 10. Demonstration of Food Safety Knowledge.

(a) Based on the risks of foodborne illness inherent to the establishment or processing plant, during inspections and upon request, the person in charge shall

demonstrate to the regulatory authority knowledge of foodborne disease prevention, application of the HACCP principles, if applicable, and the requirements of this Rule. The person in charge shall demonstrate this knowledge by compliance with this Rule, by responding correctly to the inspectors' questions as they relate to the specific establishment or processing plant, or by voluntarily being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program. The areas of knowledge may include:

(i) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;

(ii) Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;

(iii) Describing the symptoms associated with the diseases that are transmissible through food;

(iv) Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food and the prevention of foodborne illness;

(v) Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish;

(vi) Stating the required food temperatures and times for safe cooking of potentially hazardous food including meat, poultry, eggs, and fish;

(vii) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food;

(viii) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(A) Cross contamination;

(B) Hand contact with ready-to-eat foods;

(C) Handwashing; and

(D) Maintaining the establishment or processing plant in a clean condition and in good repair;

(ix) Describing foods identified as major food allergens and the

symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction.

(x) Explaining the relationship between food safety and providing equipment that is:

(A) Sufficient in number and capacity; and

(B) Properly designed, constructed, located, installed, operated, maintained, and cleaned;

(xi) Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;

(xii) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;

(xiii) Identifying poisonous or toxic materials in the establishment or processing plant and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;

(xiv) Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Rule;

(xv) Explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law, this Rule, or an agreement between the regulatory authority and the establishment or processing plant; and

(xvi) Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and exclusion or restriction of food employees.

Section 11. Person in Charge, Duties.

(a) The person in charge shall ensure that:

(i) Establishment or processing plant operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under Chapter 9, Section 42;

(ii) Persons unnecessary to the establishment or processing plant operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination;

(iii) Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with this Rule;

(iv) Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;

(v) Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt;

(vi) Employees are properly cooking potentially hazardous food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under Chapter 6, Section 38(b), and Section 48;

(vii) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within four (4) hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling;

(viii) Employees are cooking food sufficiently to ensure its safety;

(ix) Employees are properly sanitizing cleaned multi-use equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing;

(x) Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets as specified under Chapter 3, Section 53;

(xi) Except when otherwise approved as specified in Chapter 3, Section 39(b), employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use

gloves, or dispensing equipment;

(xii) Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; and

(xiii) Food employees and conditional employees are informed of their responsibility to report in accordance with law, to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food, as specified under Chapter 1, Section 12 (a).

Section 12. Health Status of Food Employees and Applicants.

(a) The license holder shall require food employees and conditional employees to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food. A food employee or conditional employee shall report the information in a manner that allows the person in charge to reduce the risk of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the food employee or conditional employee:

(i) Has any of the following symptoms:

(A) Diarrhea;

(B) Vomiting;

(C) Jaundice; or

(D) Sore throat with fever, or;

(E) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(I) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;

(II) On exposed portions of the arms, unless the lesion is protected by an impermeable cover; or

(III) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;

(ii) Has an illness diagnosed by a health practitioner due to:

(A) *Salmonella spp.*;

(B) *Shigella spp.*;

(C) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*;

(D) Hepatitis A virus; or

(E) Viral Gastroenteritis including Norovirus

(iii) Had a previous illness, diagnosed by a health practitioner:

(A) *Salmonella spp.* within the past three months,

(B) *Shigella spp.* within the past month,

(C) Shiga toxin-producing *Escherichia coli,* within the past month; or

(D) Hepatitis A virus.

(iv) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the food employee or conditional employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:

(A) Viral Gastroenteritis including Norovirus within the past 48 hours of the last exposure,

(B) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella spp.* within the past 3 days of the last exposure,

(C) *Salmonella spp*. within the past 14 days of the last exposure,

(D) Hepatitis A virus within the past 30 days of the last exposure; or

(v) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual who attends or works in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(A) Viral Gastroenteritis including Norovirus within the past 48 hours of the last exposure,

(B) Enterohemorrhagic or Shiga toxin-producing Escherichia coli, or Shigella spp. within the past 3 days of the last exposure,

(C) *Salmonella spp.* within the past 14 days of the last exposure,

(D) Hepatitis A virus within the past 30 days of the last exposure.

(b) The person in charge shall notify the regulatory authority when a food employee is:

(i) Jaundiced, or

(A) Diagnosed with a current or previous illness due to a pathogen as specified in Chapter 1, Section 12 (a) (ii) (A)-(E) or (iii) (A)-(D).

(c) The person in charge shall ensure that a conditional employee:

(i) Who exhibits or reports a symptom, or who reports a diagnosed illness as specified in Chapter 1, Section 12 (a) (i)-(iii), is prohibited from becoming a food employee until the conditional employee meets the criteria for the specific symptoms or diagnosed illness as specified in Chapter 1, Section 14; and

(ii) Who will work as a food employee in a food establishment that serves a highly susceptible population and reports a history of exposure as specified in Chapter 1, Section 12 (a) (iv)-(v), is prohibited from becoming a food employee until the conditional employee meets the criteria as specified in Chapter 1, Section 14 (a) (ix).

(d) The person in charge shall ensure that a food employee who exhibits or reports a symptom, or who reports a diagnosed illness or a history of exposure as specified in Chapter 1, Section 12 (a) (i)-(v) is:

(i) Excluded as specified in Chapter 1, Section 13 (a) (i)-(iii), and Section 13 (a) (iv) (A), (v) (A), (vi) (A), or (vii) (A) and in compliance with the provisions specified in Chapter 1, Section 14 (a) (i)-(vii); or

(ii) Restricted as specified in Chapter 1, Section 13 (a) (iv) (B), (v) (B), (vi) (B), (vii) (B), or Section 13 (a) (viii) or (ix) and in compliance with the provisions specified in Chapter 1, Section 14 (a) (iv)-(ix).

(e) A food employee or conditional employee shall report to the person in charge the information as specified in Chapter 1, Section 12 (a).

(f) A food employee shall:

(i) Comply with an exclusion as specified in Chapter 1, Section 13 (a) (i)-(iii) and Section 13 (a) (iv) (A), (v) (A), (vi) (A), or (vii) (A) and with the provisions specified in Chapter 1, Section 14 (a) (i)-(vii); or

(ii) Comply with a restriction as specified in Chapter 1, Section 13 (a) (iv) (B), (v) (B), (vi) (B), (vii) (B), or Section 13 (a) (viii) or (ix) and comply with the provisions specified in Chapter 1, Section 14 (a) (iv)-(ix).

Section 13. Exclusions and Restrictions of Food Employees.

(a) The person in charge shall exclude or restrict a food employee from an establishment or processing plant in accordance with the following:

(i) Except when the symptom is from a noninfectious condition, exclude a food employee from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles, in an establishment or processing plant if the food employee is:

(A) Symptomatic with vomiting or diarrhea; or

(B) Symptomatic with vomiting or diarrhea and diagnosed with an infection from viral gastroenteritis including Norovirus, *Shigella spp.*, or Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*.

(ii) Exclude a food employee who is:

(A) Jaundiced and the onset of jaundice occurred within the last 7 calendar days, unless the food employee provides to the person in charge written medical documentation from a health practitioner specifying that the jaundice is not caused by hepatitis A virus or other fecal-orally transmitted infection;

(B) Diagnosed with an infection from hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice; or

(C) Diagnosed with an infection from hepatitis A virus without developing symptoms.

(iii) Exclude a food employee who is diagnosed with an infection from

Salmonella spp, or reports a previous infection with *Salmonella* spp within the past 3 months as specified under Chapter 1, Section 12 (a) (iii).

(iv) If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:

(A) Exclude the food employee who works in a food establishment serving a highly susceptible population; or

(B) Restrict the food employee who works in a food establishment not serving a highly susceptible population.

(v) If a food employee is diagnosed within the past month with an infection from *Shigella* spp. and is asymptomatic:

(A) Exclude the food employee who works in a food establishment serving a highly susceptible population; or

(B) Restrict the food employee who works in a food establishment not serving a highly susceptible population.

(vi) If a food employee is diagnosed within the past month with an infection from enterohemorrhagic or shiga toxin-producing *E. coli*, and is asymptomatic:

(A) Exclude the food employee who works in a food establishment serving a highly susceptible population; or

(B) Restrict the food employee who works in a food establishment not serving a highly susceptible population.

(vii) If a food employee is ill with symptoms of acute onset of sore throat with fever:

(A) Exclude the food employee who works in a food establishment serving a highly susceptible population; or

(B) Restrict the food employee who works in a food establishment not serving a highly susceptible population.

(viii) If a food employee is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under Chapter 1, Section 12 (a) (i) (E), restrict the food employee.

(ix) If a food employee is exposed to a foodborne pathogen as

specified under Chapter 1, Section 12 (a) (iv) or (v), restrict the food employee who works in a food establishment serving a highly susceptible population.

Section 14. Removal, Adjustment, or Retention of Exclusions and Restrictions of Food Employees.

(a) The person in charge may remove, adjust, or retain the exclusion or restriction of a food employee according to the following conditions:

(i) Except when a food employee is diagnosed with an infection from hepatitis A virus or *Salmonella spp*:

(A) Reinstate a food employee who was excluded as specified under Chapter 1, Section 13 (a) (i) (A) if the food employee:

(I) Is asymptomatic for at least 48 hours; or

(II) Provides to the person in charge written medical documentation from a health practitioner that states the symptom is from a noninfectious condition.

(B) If a food employee was diagnosed with an infection from viral gastroenteritis including Norovirus and excluded as specified in Chapter 1, Section 13 (a) (i) (B):

(I) Restrict the food employee, who is asymptomatic for at least 48 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in Chapter 1, Section 14 (a) (iv) (A) or (B) are met; or

(II) Retain the exclusion for the food employee, who is asymptomatic for at least 48 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in Chapter 1, Section 14 (a) (iv) (A) or (B) are met.

(C) If a food employee was diagnosed with an infection from *Shigella* spp. and excluded as specified in Chapter 1, Section 13 (a) (i) (B):

(I) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in Chapter 1, Section 14 (a) (v) (A) or (B) are met; or

(II) Retain the exclusion for the food employee, who is

asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in Chapter 1, Section 14 (a) (v) (A) or (B) are met.

(D) If a food employee was diagnosed with an infection from Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* and excluded as specified in Chapter 1, Section 13 (a) (i) (B):

(I) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in Chapter 1, Section 14 (a) (vi) (A) or (B) are met; or

(II) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in Chapter 1, Section 14 (a) (vi) (A) or (B) are met.

(ii) Reinstate a food employee who was excluded as specified in Chapter 1, Section 13 (a) (ii) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

(A) The food employee has been jaundiced for more than 7 calendar days;

(B) The anicteric food employee has been symptomatic with symptoms other than jaundice for more than 14 calendar days; or

(C) The food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a hepatitis A virus infection.

(iii) Reinstate a food employee who was excluded as specified in Chapter 1, Section 13 (a) (iii) if:

(A) The person in charge obtains approval from the regulatory authority; and

(B) The food employee provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from *Salmonella. spp* infection as demonstrated by two (2) consecutive negative stool cultures collected at least 24 hours apart for non-typhoidal Salmonella; or three (3) consecutive negative stool cultures collected at least 24 hours apart for Salmonella sero type Typhi. If any of these cultures are positive for Typhi, exclude the employee and

repeat cultures at monthly intervals until three (3) consecutive negative cultures are obtained.

(iv) Reinstate a food employee who was excluded as specified in Chapter 1, Section 13 (a) (i) (B) or (a) (iv) (A) who was restricted in Chapter 1, Section 13 (a) (iv) (B) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

(A) The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Norovirus infection;

(B) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the food employee became asymptomatic; or

(C) The food employee was excluded or restricted and did not develop symptoms and more than 48 hours have passed since the food employee was diagnosed.

(v) Reinstate a food employee who was excluded as specified in Chapter 1, Section 13 (a) (i) (B) or (a) (v) (A) or who was restricted in Chapter 1, Section 13 (a) (v) (B) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

(A) The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a *Shigella* spp. infection based on test results showing 2 consecutive negative stool specimen cultures that are taken:

(I) Not earlier than 48 hours after discontinuance of antibiotics, and

(II) At least 24 hours apart;

(B) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 4 weeks have passed since the food employee became asymptomatic; or

(C) The food employee was excluded or restricted and did not develop symptoms and more than 4 weeks have passed since the food employee was diagnosed.

(vi) Reinstate a food employee who was excluded or restricted as specified in Chapter 1, Section 13 (a) (i) (B) or (a) (vi) (A) or who was restricted in

Chapter 1, Section 13 (a) (vi) (B) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

(A) The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of an infection from Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* based on test results that show 2 consecutive negative stool specimen cultures that are taken:

(I) Not earlier than 48 hours after discontinuance of antibiotics; and

(II) At least 24 hours apart.

(B) The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than 7 calendar days have passed since the food employee became asymptomatic; or

(C) The food employee was excluded or restricted and did not develop symptoms and more than 7 days have passed since the food employee was diagnosed.

(vii) Reinstate a food employee who was excluded or restricted as specified in Chapter 1, Section 13 (a) (vii) (A) or (B) if due to group A strep pharyngitis and the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

(A) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours;

(B) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection; or

(C) Is otherwise determined by a health practitioner to be free of a *Streptococcus pyogenes* infection.

(viii) Reinstate a food employee who was restricted as specified in Chapter 1, Section 13 (a) (viii) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

(A) An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;

(B) An impermeable cover on the arm if the infected wound or pustular boil is on the arm; or

(C) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.

(ix) Reinstate a food employee who was restricted as specified in Chapter 1, Section 13 (a) (ix) and was exposed to one of the following pathogens as specified in Chapter 1, Section 12 (a) (iv) or (v):

(A) Viral Gastroenteritis including Norovirus and one of the following conditions is met:

(I) More than 48 hours have passed since the last day the food employee was potentially exposed; or

(II) More than 48 hours have passed since the food employee's household contact became asymptomatic.

(B) *Shigella* spp. or Enterohemorrhagic or Shiga toxin producing *Escherichia coli* and one of the following conditions is met:

(I) More than 3 calendar days have passed since the last day the food employee was potentially exposed; or

(II) More than 3 calendar days have passed since the food employee's household contact became asymptomatic.

(C) *Salmonella.* spp and one of the following conditions is met:

(I) More than 14 calendar days have passed since the last day the food employee was potentially exposed; if Salmonella Typhi, a food employee must have two (2) negative stool cultures twenty four (24) hours apart; or

(II) More than 14 calendar days have passed since the food employee's household contact became asymptomatic; if Salmonella Typhi, a food employee must have two (2) negative stool cultures twenty four (24) hours apart.

(D) Hepatitis A virus and one of the following conditions is met:

(I) The food employee is immune to hepatitis A virus infection because of a prior illness from hepatitis A;

(II) The food employee is immune to hepatitis A virus

infection because of vaccination against hepatitis A;

(III) The food employee is immune to hepatitis A virus infection because of IgG administration;

(IV) More than 30 calendar days have passed since the last day the food employee was potentially exposed;

(V) More than 30 calendar days have passed since the food employee's household contact became jaundiced; or

(VI) The Food employee does not use an alternative procedure that allows bare hand contact with ready to-eat food until at least 30 days after the potential exposure, as specified in Chapter 1, Section 14 (a) (ix) (D) (IV) and (V), and the food employee receives additional training about:

(1.) Hepatitis A symptoms and preventing the transmission of infection,

(2.) Proper handwashing procedures, and

(3.) Protecting ready-to-eat food from contamination introduced by bare hand contact.

Section 15. Bed and Breakfast and Ranch Recreation Requirements.

(a) Food service provided at bed and breakfast and ranch recreation facilities shall be for the bona fide guests of said facilities and shall not be available for charge or otherwise to other members of the public that might be present.

(i) The kitchen in a bed and breakfast or ranch recreation facility in a home may be equipped the same as any normal home style kitchen provided food safety procedures can be achieved.

Section 16. State Meat and Poultry Inspection Program.

(a) As authorized by W.S. 35-7-123; 9 CFR, 321 Cooperation with States and Territories, and 9 CFR 381 Subpart R-Cooperation with States and Territories; Certification of State and Territorial Programs as at Least Equal to Federal Program, the Wyoming department of agriculture shall maintain a State Meat and Poultry Inspection Program.

(i) The director shall administer and enforce the provisions of this

Rule and shall employ or contract with such persons as may be appropriate.

(b) As authorized by 9 CFR 307.5 Overtime and Holiday Inspection Service and 307.6 Basis of Billing for Overtime and Holiday Services, the Department has the authority to charge state inspected meat and poultry plants for overtime and holiday inspection services.

(i) The owner/operator of a state inspected meat or poultry plant shall reimburse the Department for the cost of the inspection service furnished on any holiday as specified in Section 16 (b) (ii); or for more than 8 hours on any day, or more than 40 hours in any workweek Saturday through Friday.

(ii) Holidays for State employees shall be New Year's Day, January 1; Equality Day, the third Monday in January; President's Day, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25 or any other day declared to be a holiday by the Governor of Wyoming or the President of the United States. When any of the above listed holidays falls outside the basic workweek, the nearest workday within that week shall become a holiday.

(iii) Each recipient of overtime or holiday inspection service, or both, shall be billed at the rate of one and one half (1½) times the normal hourly rate of the Inspector-In-Charge for the plant making the request, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Department employee.

(iv) State inspected meat or poultry plants requesting and receiving the services of a Department employee after he or she has completed his or her day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(v) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

CHAPTER 2

REQUIREMENTS FOR PLAN SUBMISSION; LICENSE APPLICATION AND ISSUANCE; INSPECTION

Section 1. Prerequisite for Operation.

(a) A person shall not operate an establishment or processing plant without a valid license issued by the regulatory authority.

(i) When a person operates two (2) or more establishments or two (2) or more processing plants not on the same premises in this state, a separate license shall be required for each.

(ii) A person conducting two (2) or more operations on the same premises in this state may operate under one (1) license.

Section 2. Submission and Contents of the License Application.

(a) Pursuant to W.S. 35-7-124(a), any person processing, distributing, storing or preparing food for wholesale or retail use shall obtain a license from the department of agriculture or a local health department. The license is not transferable, shall be renewed on an annual basis and shall be prominently displayed in the establishment or processing plant. No establishment or processing plant shall serve, hold for sale or sell food to the public without a valid license. An agriculture producer shall be exempt from the licensure requirement in this Section for processing, distributing, storing or sale of any raw agriculture commodity he produces.

(i) Milk haulers, graders, and testers shall be licensed according to Chapter 2, Section 2, and standardized by the department of agriculture using criteria specified in the United States Public Health Service/FDA Pasteurized Milk Ordinance, Appendix B -Milk Production; Hauling; Industry Inspection.

(ii) Any person candling eggs in the state of Wyoming shall be licensed according to Chapter 2, Section 2, and standardized by the department of agriculture using criteria specified in USDA AMS 56- U.S. Standards, Grades, and Weight Classes for Shell Eggs and 7 CFR Part 56 Regulations Governing the Voluntary Grading of Shell Eggs.

(b) Pursuant to W.S. 35-7-124(b), written application for a new license shall be made on a form approved by the department of agriculture and provided by the department of agriculture or the local health department and shall be signed by the applicant.

(i) The application shall include:

(A) The name, mailing address, telephone number, and signature of the person applying for the license; the name, mailing address, and telephone number of the registered agent; and the name, mailing address, and location of the establishment or processing plant;

(B) Information specifying whether the establishment or processing plant is owned by an association, corporation, individual, partnership, or other legal entity;

(C) A statement specifying whether the establishment or processing plant:

(I) Is mobile or stationary and temporary or permanent; and

(II) Is an operation that includes one or more of the following:

(1.) Prepares, offers for sale, or serves potentially hazardous food:

a. Only to order upon a consumer's request;

b. In advance in quantities based on projected consumer demand and discards food that is not sold or served at an approved frequency; or

c. Using time as the public health control as specified under Chapter 3, Section 61;

(III) Prepares potentially hazardous food in advance using a food preparation method that involves two or more steps which may include combining potentially hazardous ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing;

(IV) Prepares food as specified under Chapter 2, Section 2 (b)(i)(C)(III), for delivery to and consumption at a location off the premises of the establishment where it is prepared;

(V) Prepares food as specified under Chapter 2, Section 2(b) (i)(C)(III), for service to a highly susceptible population;

(VI) Prepares only food that is not potentially hazardous; or

(VII) Does not prepare, but offers for sale only prepackaged food that is not potentially hazardous;

(D) A statement signed by the applicant that:

(I) Certifies to the accuracy of the information provided in the application; and

(II) Affirms that the applicant will:

(1.) Comply with this Rule; and

(2.) Allow the regulatory authority access to the establishment as specified under Chapter 2, Section 24, and to the records specified under Chapter 3, Section 15, Chapter 8, Section 21, and Chapter 10, Section 2 (a) (iv) (F).

Section 3. Qualifications and Responsibilities of Applicants.

(a) To qualify for a license, an applicant shall:

(i) Be an owner of the establishment or the person legally in charge of the business entity;

(ii) Comply with the requirements of this Rule;

(iii) As specified under Chapter 2, Section 24, agree to allow access to the establishment or processing plant and to provide required information; and

(iv) Pay the applicable license fees at the time the application is submitted.

Section 4. Issuance of a License.

(a) For establishments or processing plants that are required to submit plans as specified under Chapter 2, Section 6, the regulatory authority shall issue a license to the applicant after:

(i) A properly completed application is submitted;

(ii) The required fee is submitted;

(iii) The required plans, specifications, and information are reviewed and approved; and

(iv) A pre-operational inspection shows that the establishment or processing plant is built or remodeled in accordance with the approved plans and specifications and that the establishment is in compliance with this Rule.

(b) The regulatory authority may renew a license for an existing establishment or processing plant or may issue a license to a new owner of an existing establishment or processing plant after:

(i) A properly completed application is submitted, reviewed, and approved;

(ii) The required fees are submitted; and

(iii) An inspection shows that the establishment or processing plant is in compliance with this Rule.

Section 5. License Fees.

(a) For establishments or processing plants that are required to have a license, as specified under Chapter 2, Section 1 (a), the regulatory authority shall issue a license to the applicant after the appropriate license fee is submitted.

(b) The license fee schedule is as follows:

(i) All establishments that are new, have a new owner or have changed location shall pay an initial license fee of $100.00 with an annual license renewal fee of $50.00;

(ii) Temporary establishment license fees shall be $25.00; and

(iii) Temporary sampling establishment license fees shall be $25.00.

Section 6. When Plans and Specifications Are Required.

(a) A license applicant or license holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:

(i) The construction of an establishment or processing plant;

(ii) The conversion of an existing structure for use as an establishment

or processing plant; or

(iii) The remodeling of an establishment or processing plant or a change of type of the establishment or processing plant as specified under Chapter 2, Section 7, if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this Rule.

Section 7. Contents of the Plans and Specifications.

(a) The plans and specifications for an establishment or processing plant, including an establishment or processing plant specified under Chapter 10, Section 1, shall include, as required by the regulatory authority based on the type of operation, type of food preparation, and foods prepared, the following information to demonstrate conformance with Rule provisions:

(i) Intended menu;

(ii) Anticipated volume of food to be stored, prepared, and sold or served;

(iii) Proposed layout, mechanical schematics, construction materials, and finish schedules;

(iv) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;

(v) Evidence that standard procedures that ensure compliance with the requirements of this Rule are developed or are being developed; and

(vi) Other information that may be required by the regulatory authority for the proper review of the proposed construction, conversion or modification, and procedures for operating an establishment or processing plant.

Section 8. Approval of Plans and Specifications.

(a) The regulatory authority shall review all plans and specifications to determine if they are in compliance with this Rule. After reviewing the plans and specifications, the regulatory authority shall:

(i) Complete a plan review sheet.

(b) If the plans and specifications are approved, the regulatory authority shall submit a copy of the plan review sheet denoting approval to the license applicant or

license holder.

(c) If the plans and specifications are disapproved, a copy of the plan review sheet stating the reason for disapproval shall be sent to the license applicant or license holder.

Section 9. Pre-operational Inspections.

(a) The regulatory authority shall conduct one or more pre-operational inspections to verify that the establishment or processing plant is constructed and equipped in accordance with the approved plans and approved modifications of those plans and is in compliance with law and this Rule.

(b) The regulatory authority shall conduct a pre-opening inspection prior to issuance of a license.

(i) A routine inspection shall be performed within thirty (30) days after the pre-opening inspection.

Section 10. Application for Official Inspection, Granting Inspection, Official Numbers.

(a) Inspection at official establishments shall be performed by the director, as authorized by 9 CFR 321 Cooperation With States and Territories.

(b) To qualify for official inspection, as specified in 9 CFR 304 Application For Inspection; Grant of Inspection an applicant shall:

(i) Submit a completed application furnished by the director;

(ii) Comply with the requirements of this Rule in addition to 9 CFR 304 Application for Inspection; Grant of Inspection;

(iii) Comply with the requirements of 9 CFR 304.3 Conditions for Receiving Inspection, including:

(A) Developing written Sanitation Standard Operating Procedures, as specified in 9 CFR 416 Sanitation;

(B) Conduct a hazard analysis and have developed and validated a HACCP plan, as required in 9 CFR 417 Hazard Analysis and Critical Control Point (HACCP) Systems.

(iv) Comply with the requirements of 9 CFR 305.3 Sanitation and adequate facilities.

(c) To each official establishment granted inspection, the director shall:

(i) Give notice in writing to each applicant.

(ii) Assign an official number to each official establishment as specified in 9 CFR 305.1 Official numbers; subsidiaries and tenants.

(A) Such number shall be used to identify all inspected and passed products prepared in the establishment;

(B) More than one (1) number shall not be assigned to an establishment; and

(C) Numbers designating all establishments shall be determined by the director, and appropriately placed on all of the inspection stamps designed for each establishment.

(d) Each official establishment granted inspection shall be separate and distinct from any unofficial establishment as specified in 9 CFR 305.2 Separation of official establishments.

(e) To each official establishment granted inspection, the director shall inaugurate and assign inspection, as specified in 9 CFR 305.4 Inauguration of inspection and 9 CFR 306 Assignment and authorities of program employees.

(f) As specified in 9 CFR 307.4 Schedule of operations, no operation requiring inspection shall be conducted except under the supervision of the director.

(g) All slaughtering of animals and preparation of products produced under inspection shall be done within reasonable hours and with reasonable speed, considering the official establishment's facilities.

Section 11. Denial of License Application, Notice.

(a) The director may by order deny a license application if he finds:

(i) The applicant has made false statements on the license application;

(ii) The applicant has violated or failed to comply with any provision of law;

(iii) The applicant is the subject of an order within the past two (2) years of any regulatory authority in this state or any other denying, suspending or revoking a food license;

(iv) The applicant has failed to submit the appropriate fees; or

(v) The applicant has failed to correctly and completely fill out the application.

(b) If a license application is denied, the regulatory authority shall provide the applicant with a notice that includes:

(i) The specific reasons and rule citations for the license application denial;

(ii) The actions, if any, that the applicant must take to qualify for a license application;

(iii) Advisement of the applicant's right to request a hearing before the director;

(iv) The time, place and nature of hearing;

(v) The legal authority under which the hearing is to be held; and

(vi) A short plain statement of the matters asserted.

(c) The applicant must request a hearing within twenty (20) days of the receipt of the director’s notice.

(d) If a hearing is requested the director shall schedule a time and place for the hearing, to be held not later than thirty (30 days) from the date of the request unless a later date is agreed to by the parties.

(e) If the applicant supplies evidence of correction and all other license requirements have been met a license shall be issued.

(f) The applicant shall be notified of the time, date and place of the hearing at least seven (7) days before the date of the hearing.

Section 12. Responsibilities of the License Holder.

(a) Upon acceptance of the license issued by the regulatory authority, the license holder in order to retain the license shall:

(i) Post the license in a location in the establishment or processing plant that is conspicuous to consumers;

(ii) Comply with the provisions of this Rule including the conditions of a granted variance as specified under Chapter 1, Section 6, and approved plans as specified under Chapter 2, Section 8;

(iii) Comply with the plan as specified under Chapter 1, Section 6, if an establishment or processing plant is required under Chapter 10, Section 1, to operate under a HACCP Plan;

(iv) Immediately contact the regulatory authority to report an illness of a food employee applicant or food employee as specified under Chapter 1, Section 15;

(v) Immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist as specified under Chapter 2, Section 13;

(vi) Allow representatives of the regulatory authority access to the establishment as specified under Chapter 2, Section 24;

(vii) Except as specified under Chapter 2, Section 12 (a)(viii), replace existing facilities and equipment specified in Chapter 1, Section 4(b), with facilities and equipment that comply with this Rule if:

(A) The regulatory authority directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted;

(B) The regulatory authority directs the replacement of the facilities and equipment because of a change of ownership; or

(C) The facilities and equipment are replaced in the normal course of operation;

(viii) Comply with directives of the regulatory authority including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the regulatory authority in regard to the license holder's establishment or processing plant or in response to community emergencies;

(ix) Accept notices issued and served by the regulatory authority according to law; and

(x) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this Rule or a directive of the

regulatory authority, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

Section 13. Ceasing Operations and Reporting.

(a) Except as specified in Chapter 2, Section 13 (b), a license holder shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency such as, but not limited to, a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, or gross insanitary occurrence or condition.

(b) A license holder need not discontinue operations in an area of an establishment or processing plant that is unaffected by the imminent health hazard.

Section 14. Resumption of Operations.

(a) If operations are discontinued as specified under Chapter 2, Section 13, or otherwise according to law, the license holder shall obtain approval from the regulatory authority before resuming operations.

Section 15. Conditions Warranting Remedy.

(a) The regulatory authority may seek an administrative or judicial remedy including an administrative meeting to achieve compliance with the provisions of this Rule if a person operating an establishment or processing plant or an employee:

(i) Fails to have a valid license to operate an establishment or processing plant as specified under Chapter 2, Section 1;

(ii) Violates any term or condition of a license as specified under Chapter 2, Section 12;

(iii) Allows serious or repeated rule violations to remain uncorrected beyond time frames for correction approved, directed, or ordered by the regulatory authority under Chapter 2, Sections 26 and 28;

(iv) Fails to comply with a regulatory authority order issued concerning an employee suspected of having a disease transmissible through food by infected persons;

(v) Fails to comply with an order issued as a result of a hearing for an

administrative remedy;

(vi) Fails to comply with a summary suspension order issued by the regulatory authority as specified in Chapter 2, Sections 17; or

(vii) Fails to comply with any other rule or regulation.

Section 16. Administrative Meetings.

(a) The Wyoming Department of Agriculture may initiate an administrative meeting for the licensee's failure to:

(i) Correct critical violations from a routine inspection if there is a history of non-compliance with this Rule;

(ii) For refusal to grant access by the regulatory authority; or

(iii) If an inspection reveals deviations in the HACCP plan.

(b) Notice of administrative meeting shall state:

(i) The reasons for the notice of administrative meeting with reference to the provisions of the rules that are in violation;

(ii) The location and time the administrative meeting will be held; and

(iii) The licensee may appear in person or by or with counsel licensed to practice in the State of Wyoming.

(c) The Wyoming Department of Agriculture will administer the administrative meeting and hear opposing opinions regarding the issue in question.

(d) The purpose of the administrative meeting is to facilitate a mutually agreed upon plan of compliance for the license holder.

(e) The plan of compliance shall be:

(i) Presented, in writing to the license holder after the meeting;

(ii) Effective immediately upon presentation with a correction completion date ten (10) business days from the presentation date at which time a re-inspection will be performed; and

(iii) Signed by both the license holder and the regulatory authority.

(f) The administrative meeting may have three (3) possible outcomes:

(i) A mutually agreed upon plan of compliance with a re-inspection date;

(ii) No agreement of cooperation by the license holder resulting in a revocation notice being issued; or

(iii) Dismissal of the meeting by the Wyoming Department of Agriculture.

(g) If no agreement is reached between the Wyoming Department of Agriculture and the license holder or the re-inspection finds the plan of compliance has been ignored, a revocation notice shall be issued within ten (10) business days of the no agreement date or the re-inspection date.

Section 17. Summary Suspension.

(a) The regulatory authority may summarily suspend a license to operate an establishment or processing plant if it determines through inspection, or examination of food employees, food, records, or other means as specified in this Rule, that an imminent health hazard exists including, but not limited to, fire, flood, extended interruption of electrical or water service, sewage backup, or after consultation with the Health Officer.

(i) The regulatory authority may summarily suspend a license by providing written notice of the summary suspension to the license holder or the person in charge without prior warning, notice of a hearing, or a hearing.

(ii) A summary suspension notice shall state:

(A) That the license is immediately suspended and that all operations shall immediately cease;

(B) The reasons for summary suspension with reference to the provisions of this Rule that are in violation;

(C) The type of imminent threat to the public health that may be caused by the violation;

(D) The name and address of the regulatory authority representative to whom notice for re-inspection may be made and who may certify that reasons for the suspension are eliminated;

(E) The license holder may request a contested case hearing

within five (5) business days of the summary suspension. The regulatory authority shall hold a hearing, if requested, within ten (10) business days of the summary suspension; and

(F) The name and address of the regulatory authority representative to whom a request for a contested case hearing may be made.

(iii) The regulatory authority shall conduct a re-inspection of the establishment or processing plant for which the license was summarily suspended within 48 hours after receiving notice from the license holder stating that the conditions cited in the summary suspension order no longer exist.

(iv) A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and their elimination has been confirmed by the regulatory authority through re-inspection and other means as appropriate or until a court of competent jurisdiction otherwise orders.

(v) The suspended license shall be reinstated immediately if the regulatory authority determines that the imminent health hazard no longer exists. A notice of reinstatement shall be provided to the license holder or person in charge.

Section 18. Revocation.

(a) The Wyoming Department of Agriculture may initiate revocation proceedings for a license:

(i) If the condition for the summary suspension is not corrected;

(ii) For failure to correct critical violations from a routine inspection;

(iii) If there is a history of non-compliance with this Rule; or

(iv) For refusal to grant access by the regulatory authority.

(b) The revocation notice shall state:

(i) That the license shall be revoked fifteen (15) calendar days after receipt of the revocation notice and that all operations shall cease at that time unless a contested case hearing is requested;

(A) The revocation notice shall be sent by certified mail, return receipt requested;

(ii) The reasons for revocation with reference to the provisions of this

Rule that are in violation;

(iii) That the license holder may request a hearing by submitting a request within fifteen (15) days of the receipt of the notice of revocation;

(iv) The name and address of the Wyoming Department of Agriculture representative to whom a request for a hearing may be made;

(v) If a hearing is requested, the hearing shall be conducted by a hearing officer in accordance with the Wyoming Administrative Procedure Act, W.S. 16-3-107 through 115 and the Rules of Practice and Procedures of the Wyoming Department of Agriculture; and

(vi) The licensee may appear in person or by or with counsel licensed to practice in the State in Wyoming.

(c) The final decision, accompanied by written findings of fact and conclusions of law and order, shall be issued by the director of the Wyoming Department of Agriculture.

(d) The final decision shall be delivered to the license holder by certified mail, return receipt requested.

Section 19. Hearings.

(a) All hearings provided for in this Rule shall be conducted in accordance with the Rules of Practice and Procedures adopted by the Wyoming Department of Agriculture. Appeal from any final order of the Wyoming Department of Agriculture shall be taken as provided by the Wyoming Administrative Procedure Act.

Section 20. Service of Notices.

(a) A notice issued in accordance with this Rule, except for a notice of summary suspension which shall be considered properly served pursuant to Chapter 2, Section 17, shall be considered to be properly served if it is served by one of the following methods:

(i) The notice is personally served by the regulatory authority, a law enforcement officer, or a person authorized to serve a civil process to the license holder, the person in charge, or person operating an establishment or processing plant without a license;

(ii) The notice is sent by the regulatory authority to the last known

address of the license holder or the person operating an establishment or processing plant without a license, by registered or certified mail return receipt requested or by other public means so that a written acknowledgment of receipt may be acquired;

(iii) If the notice is unable to be delivered after reasonable attempts to serve, then the notice shall be clearly posted by the regulatory authority at a public entrance to the establishment or processing plant; or

(iv) The notice is provided by the regulatory authority in accordance with another manner of service authorized in law.

Section 21. When Service is Effective.

(a) Service is effective at the time of the receipt of the notice or at the time of the posting of the notice.

Section 22. Establishing Inspection Interval.

(a) Except as specified under Chapter 2, Section 22 (b) and (c), and Section 10 (f), the regulatory authority may inspect an establishment or processing plant at least once every six (6) months.

(b) The regulatory authority may increase the interval between inspections beyond six (6) months but in no event less than once a year if:

(i) The establishment or processing plant is fully operating under an approved and validated HACCP plan as specified under Chapter 1, Section 7(a)(i) and (ii), and Chapter 10, Section 1;

(ii) The establishment or processing plant is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every six (6) months the establishment or processing plant is contacted by telephone or other means by the regulatory authority to ensure that the establishment or processing plant manager and the nature of operation are not changed; or

(iii) The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not potentially hazardous such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.

(c) The regulatory authority shall periodically inspect throughout the license period a temporary establishment that:

(i) Prepares, sells, or serves unpackaged potentially hazardous food;

(ii) Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or

(iii) Has inexperienced food employees.

Section 23. Performance and Risk-Based Inspections.

(a) Within the parameters specified under Chapter 2, Section 22, the regulatory authority shall prioritize and conduct more frequent inspections based upon its assessment of an establishment's or processing plant's history of compliance with this Rule and the establishment's or processing plant's potential as a vector of foodborne illness by evaluating:

(i) Past performance, for nonconformance with this Rule or HACCP plan requirements that are critical;

(ii) Past performance, for numerous or repeat violations of this Rule or HACCP plan requirements that are noncritical;

(iii) Past performance, for complaints investigated and found to be valid;

(iv) The hazards associated with the particular foods that are prepared, stored, or served;

(v) The type of operation including the methods and extent of food storage, preparation, and service;

(vi) The number of people served; and

(vii) Whether the population served is a highly susceptible population.

Section 24. Access for Inspection.

(a) After the regulatory authority presents official credentials and states the purpose of, and an intent to conduct an inspection, the person in charge shall allow the regulatory authority to determine if the establishment or processing plant is in compliance with this Rule by:

(i) Allowing access to the establishment or processing plant;

(ii) Allowing inspection; and

(iii) Providing information and records specified in this Rule and to which the regulatory authority is entitled according to law, during the establishment's or processing plant's hours of operation and other reasonable times.

(b) Denial of access to inspect shall be grounds for revocation of a license.

(c) The details of the denial of access shall be recorded on the inspection report form.

Section 25. Documenting Information and Observations.

(a) The regulatory authority shall document on an inspection report form:

(i) Administrative information about the establishment's or processing plant's legal identity, street and mailing addresses, type of establishment or processing plant and operation as specified under Chapter 2, Section 2(b), inspection date, and other information such as type of water supply and sewage disposal, status of the license, and personnel certificates that may be required; and

(ii) Specific factual observations of violative conditions or other deviations from this Rule that require correction by the license holder including but not limited to:

(A) Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention and the requirements of this Rule specified under Chapter 1, Section 10;

(B) Failure of food employees and the person in charge to demonstrate their knowledge of their responsibility to report a disease or medical condition as specified under Chapter 1, Sections 15 and 16;

(C) Nonconformance with critical items of this Rule;

(D) Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the regulatory authority as specified under Chapter 1, Section 7;

(E) Failure of the person in charge to provide records required by the regulatory authority for determining conformance with a HACCP plan as specified

under Chapter 10, Section 2(a)(iv)(F);

(F) Nonconformance with critical limits of a HACCP plan; and

(G) Nonconformance with any other rule or regulation.

Section 26. Timely Correction for Critical Item Violation.

(a) Except as specified in Chapter 2, Section 26 (b), a license holder shall at the time of inspection correct a critical violation of this Rule or implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.

(b) Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed ten (10) calendar days after the inspection, for the license holder to correct critical violations of this Rule or HACCP plan deviations.

(i) If a determination by the inspector that the corrective action cannot be completed within 10 (ten) days, the inspector may request an extension be granted which must be approved in writing by a supervisor.

Section 27. Verification and Documentation of Correction for Critical Item Violation.

(a) After observing at the time of inspection a correction of a critical item violation or HACCP plan deviation, the regulatory authority shall enter the violation and information about the corrective action on the inspection report.

(b) After receiving notification that the license holder has corrected a critical item violation or HACCP plan deviation, or at the end of the specified period of time, the regulatory authority shall verify correction of the violation, document the information on an inspection report, and enter the report in the regulatory authority's records.

Section 28. Time Frame for Correction for Noncritical Violation.

(a) Except as specified in Chapter 2, Section 28 (b), the license holder shall correct noncritical violations by a date and time agreed to or specified by the regulatory authority but no later than ninety (90) calendar days after the inspection.

(b) The regulatory authority may approve a compliance schedule that extends beyond the time limits specified under Chapter 2, Section 26 (b), if a written schedule of compliance is submitted by the license holder and no health hazard exists or will result

from allowing an extended schedule for compliance.

Section 29. Issuing Report and Obtaining Acknowledgment of Receipt.

(a) At the conclusion of the inspection, the regulatory authority shall provide a copy of the completed inspection report to the license holder or to the person in charge, and request a signed acknowledgment of receipt.

Section 30. Refusal to Sign Acknowledgment.

(a) The regulatory authority shall:

(i) Inform a person who declines to sign an acknowledgment of receipt of inspection findings that:

(A) An acknowledgment of receipt is not an agreement with findings;

(B) Refusal to sign an acknowledgment of receipt will not affect the license holder's obligation to correct the violations noted in the inspection report within the time frames specified; and

(C) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the regulatory authority's historical record for the establishment or processing plant.

Section 31. Public Information.

(a) Except as specified in Chapter 10, Section 3, the completed inspection report form is a public document that shall be made available for public disclosure to any person who requests it according to law.

Section 32. Examining, Sampling, and Testing Food.

(a) The regulatory authority may examine, sample, and test food in order to determine its compliance with this Rule.

CHAPTER 3

FOOD CARE

Section 1. Compliance with Food Law.

(a) Food shall be obtained from sources that comply with law.

(b) Food prepared in a private home may not be used or offered for human consumption in an establishment.

(c) Packaged food shall be labeled as specified in law, including the Wyoming Food, Drug and Cosmetic Safety Act, W.S. 35-7-110 through 35-7-127, 7 CFR 60 Country of Origin Labeling for Fish and Shellfish, 7 CFR 65 Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Macadamia Nuts, and Peanuts, 21 CFR 101 Food Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under Chapter 3, Sections 11 and 12.

(d) Fish, other than molluscan shellfish, that are intended for consumption in their raw or undercooked form and allowed as specified in Chapter 3, Section 41(d), may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under Chapter 3, Section 34; or frozen on the premises as specified under Chapter 3, Section 34, and records are retained as specified under Chapter 3, Section 35.

(e) Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in Chapter 3, Section 41(c) shall be:

(i) Obtained from a processing plant that, upon request by the purchaser, packages the steaks and labels them to indicate that the steaks meet the definition of whole-muscle, intact beef; or

(ii) Deemed acceptable by the regulatory authority based on other evidence such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef, and

(iii) If individually cut in a food establishment:

(A) Cut from whole-muscle intact beef that is labeled by a processing plant as specified in Chapter 3, Section 1(e)(i) or identified as specified in Chapter 3, Section 1(e) (ii);

(I) Prepared so they remain intact; and

(II) If packaged for undercooking in an establishment, labeled as specified in Chapter 3, Section 1 (e) (i) or identified as specified in Chapter 3, Section 1(e) (ii).

(f) Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2 Labels: definitions; required features, and 9 CFR 381.125 Special handling labeling requirements.

(g) Eggs that have not been specifically treated to destroy all viable *Salmonellae* shall be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

(h) Food shall be safe, unadulterated, and as specified in Chapter 3, Section 65, honestly presented

Section 2. Food in a Hermetically Sealed Container.

(a) Food in a hermetically sealed container shall be obtained from a processing plant that is regulated by the regulatory authority.

Section 3. Wild Mushrooms.

(a) Except as specified in Chapter 3, Section 3(b), mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert.

(b) This section does not apply to:

(i) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the regulatory authority; or

(ii) Wild mushroom species if they are in packaged form and are the product of a processing plant that is regulated by the regulatory authority.

Section 4. Animals Slaughtered and Processed Under Inspection.

(a) All animals except poultry slaughtered and processed for sale shall have antemortem and postmortem inspection and shall meet the requirements of 9 CFR 313, Humane Slaughter of Livestock, 9 CFR 309, Antemortem Inspection, 310 Postmortem Inspection, and 311 Disposal of Diseased or Otherwise Adulterated Carcasses and Parts.

(i) All animals except poultry slaughtered and processed under Inspection shall be conducted in accordance with this Rule by the Wyoming department of agriculture except as specified in 9 CFR 302 Application of Inspection and Other Requirements and 9 CFR 303 Exemptions.

(A) Exempt establishments handling wild game shall:

(I) Conduct operations in accordance with this Rule and 9 CFR 302 Application of Inspection and Other Requirements and 9 CFR 303 Exemptions;

(II) Be required to hold, process, identify, and prepare Wild game separately from all domestic animal carcasses, meat, meat food or meat food by-products;

(III) Labeled and identified as “wild game,” or by the species of wild game, “antelope,” “deer,” “elk,” “moose,” “bear,” etc.;

(IV) Store the heads, horns, capes, feet, skins, or any part thereof in closed containers and shall not create an offensive condition or odor; and

(V) Process wild game meat which is abandoned Pursuant to W.S. 23-3-303.

(b) All poultry slaughtered and processed for sale shall have antemortem and postmortem inspection and shall meet the requirements of 9 CFR 381, Subpart J Antemortem Inspection, Subpart K Postmortem Inspection; Disposition of Carcasses and Parts; except as specified in 9 CFR 381.6 Establishments Requiring Inspection and 9 CFR 381.10 Exemptions.

(c) A voluntary inspection program shall be administered and performed by the Wyoming department of agriculture and meeting the requirements of the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR 352 Exotic Animals; Voluntary Inspection or rabbits that are "inspected and certified" in accordance with 9 CFR 354 Voluntary Inspection of Rabbits and Edible Products Thereof shall be performed.

(d) An animal may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and Threatened Wildlife and Plants.

(e) Meat or meat food products capable of use as human food shall meet the requirements specified in 9 CFR 325, Transportation.

Section 5. Rendering.

(a) Rendering of carcasses and parts shall be done in accordance with 9 CFR 315 Rendering or Other Disposal of Carcasses and Parts Passed for Cooking.

Section 6. Additives.

(a) As specified in law including the Wyoming Food, Drug and Cosmetic Safety Act, W. S. 35-7-110 through 35-7-127, food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170-180 relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR 185 Tolerances for Pesticides in Food.

Section 7. Package Integrity.

(a) Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants.

Section 8. Fluid Milk and Milk Products.

(a) Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in the United States Public Health Service/FDA Grade A Pasteurized Milk Ordinance.

(b) Fluid and dry milk and milk products complying with Grade A standards as specified in United States Public Health Service/FDA Grade A Pasteurized Milk Ordinance shall be obtained pasteurized.

(c) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135 - Frozen Desserts.

(d) Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 - Cheeses and Related Cheese Products, for curing certain cheese varieties.

(e) Grade A milk and milk for manufacturing purposes shall meet the requirements of the United States Public Health Service/FDA Grade A Pasteurized Milk Ordinance and Grade A Condensed and Dry Milk Ordinance.

(f) Milk produced for processing and manufacturing into products for human consumption shall meet the requirements of the United States Department of Agriculture/Agriculture Marketing Service Milk for Manufacturing Purposes and its Production and Processing.

(g) Unpasteurized milk and products made from unpasteurized milk (except cheese qualifying under subsection (d)) may not be sold, delivered, served, or provided for human consumption.

(i) This subsection does not apply to individuals who obtain milk from animals owned by them, members of their family, or their employer and who furnish raw milk or products made from raw milk only to members of their family or non-paying guests.

Section 9. Fish.

(a) Fish that are received for sale or service shall be:

(i) Commercially and legally caught or harvested; or

(ii) Approved by the regulatory authority.

Section 10. Molluscan Shellfish.

(a) Molluscan shellfish shall be obtained from sources which meet the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(b) Molluscan shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

(c) Molluscan shellfish that are recreationally caught may not be received for sale or service.

Section 11. Shucked Shellfish, Packaging and Identification.

(a) Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the:

(i) Name, address, and certification number of the shucker-packer, or repacker, of the molluscan shellfish; and

(ii) The "sell by" date for packages with a capacity of less than one-half (2) gallon (1.87l) or the date shucked for packages with a capacity of one-half (2) gallon (1.87 l) or more.

(b) A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified under Chapter 3, Section 11(a), shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

Section 12. Shellstock Identification.

(a) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list:

(i) Except as specified under Chapter 3, Section 12(c), on the harvester's tag or label, the following information in the following order:

(A) The harvester's identification number that is assigned by the shellfish control authority;

(B) The date of harvesting;

(C) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested;

(D) The type and quantity of shellfish; and

(E) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for ninety (90) days;

(ii) Except as specified in Chapter 3, Section 12(d), on each dealer's tag or label, the following information in the following order:

(A) The dealer's name and address, and the certification number assigned by the shellfish control authority;

(B) The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested;

(C) The same information as specified for a harvester's tag under Chapter 3, Section 12(a)(i)(B)-(D); and

(D) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for ninety (90) days.

(b) A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under Chapter 3, Section 12(a), shall be subject to a hold order pursuant to W.S. 35-7-114, or seizure and destruction in accordance with 21 CFR Subpart D -Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

(c) If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.

(d) If the harvester's tag or label is designed to accommodate each dealer's identification as specified under Chapter 3, Section 12 (a)(ii)(A) and (B), individual dealer tags or labels need not be provided.

Section 13. Shellstock, Condition.

(a) When received by an establishment, shellstock shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded.

Section 14. Molluscan Shellfish, Original Container.

(a) Except as specified in Chapter 3, Section 14(b) and (c), molluscan shellfish may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(b) For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

(i) The source of the shellstock on display is identified as specified under Chapter 3, Section 12, and recorded as specified under Chapter 3, Section 15; and

(ii) The shellstock are protected from contamination.

(c) Shucked shellfish may be removed from the container in which they were

received and held in a display container from which individual servings are dispensed upon a consumer's request if:

(i) The labeling information for the shellfish on display as specified under Chapter 3, Section 11, is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

(ii) The shellfish are protected from contamination.

(d) Shucked shellfish may be removed from the container in which they were received and repacked in consumer self service containers where allowed by law if:

(i) The labeling information for the shellfish is on each consumer self service container as specified in Chapter 3, Section 11 and in Chapter 4, Section 1 (a) and (b) (i)-(v);

(ii) The labeling information as specified Chapter 3, Section 11 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

(iii) The labeling information and dates specified in Chapter 3, Section 14 (d) (ii) are maintained for 90 days; and

(iv) The shellfish are protected from contamination.

Section 15. Shellstock, Maintaining Identification.

(a) Except as specified under Chapter 3, Section 15(b)(ii), shellstock tags shall remain attached to the container in which the shellstock are received until the container is empty.

(b) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for ninety (90) calendar days from the dates of harvest:

(i) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the shellstock are sold or served; and

(ii) If shellstock are removed from their tagged or labeled container:

(A) Preserves source identification by using a record keeping system as specified under Chapter 3, Section 15(b)(i); and

(B) Ensures that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers, different harvest dates, or different growing areas as identified on the tag or label before being ordered by the consumer.

Section 16. Eggs.

(a) Shell eggs shall conform to the requirements of 7 CFR 57 Inspection of Eggs (Egg Products Inspection Act), 7 CFR Part 56 Regulations Governing the Voluntary Grading of Shell Eggs and USDA AMS 56 U.S. Standards, Grades, and Weight Classes for Shell Eggs.

(b) Liquid, frozen, and dry eggs and egg products shall be obtained pasteurized.

Section 17. Packaged and Unpackaged Food; Separation, Packaging, and Segregation.

(a) Food shall be protected from cross contamination by:

(i) Except as specified in (i) (C) below, separating raw animal foods during storage, preparation, holding, and display from:

(A) Raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as vegetables; and

(B) Cooked ready-to-eat food;

(C) Frozen, commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.

(ii) Except when combined as ingredients, separating types of raw animal food from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

(A) Using separate equipment for each type; or

(B) Arranging each type of food in equipment so that cross contamination of one type with another is prevented; and

(C) Preparing each type of food at different times or in separate

areas;

(iii) Cleaning equipment and utensils as specified under Chapter 7, Section 1, and sanitizing as specified under Chapter 7, Section 17;

(iv) Except as specified in Chapter 3, Section 17(b), storing the food in packages, covered containers, or wrappings;

(v) Cleaning hermetically sealed containers of food of visible soil before opening;

(vi) Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(vii) Storing damaged, spoiled, or recalled food being held in the food establishment as specified under Chapter 3, Section 22;

(viii) Separating fruits and vegetables, before they are washed as specified under Chapter 3, Section 40, from ready-to-eat food; and

(ix) The use of burlap as a wrapping for meat will not be permitted unless the meat is first wrapped with a food grade paper or cloth which will prevent contamination with lint or other foreign matter.

(b) Chapter 3, Section 17(a) (iv), does not apply to:

(i) Whole, uncut, raw fruits and vegetables and nuts in the shell that require peeling or hulling before consumption;

(ii) Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks; smoked or cured sausages that are placed on clean, sanitized racks;

(iii) Food being cooled as specified under Chapter 3, Section 32(b) (ii); or

(iv) Shellstock.

Section 18. Preventing Contamination when Tasting.

(a) A food employee may not use a utensil more than once to taste food that is to be sold or served.

Section 19. Temperature Requirements.

(a) Except as specified in Chapter 3, Section 19(b), refrigerated, potentially hazardous food shall be at a temperature of 41°F (5°C) or below when received.

(b) If a temperature other than 41°F (5°C) for a potentially hazardous food is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, the food may be received at the specified temperature.

(c) Raw eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 45ºF (7ºC) or less.

(d) Potentially hazardous food that is cooked to a temperature and for a time specified under Chapter 3, Section 41 through 43, and received hot shall be at a temperature of 135ºF (57.2ºC) or above.

(e) A food that is labeled frozen and shipped frozen by a processing plant shall be received frozen.

(f) Upon receipt, potentially hazardous food shall be free of evidence of previous temperature abuse.

Section 20. Protection from Unapproved Additives.

(a) Food shall be protected from contamination that may result from the addition of, as specified in Chapter 3, Section 6:

(i) Unsafe or unapproved food or color additives; and

(ii) Unsafe or unapproved levels of approved food and color additives.

(b) A food employee may not:

(i) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B_1; or

(ii) Serve or sell food specified under Chapter 3, Section 20(b)(i), that is treated with sulfiting agents before receipt by the establishment, except that grapes need not meet this subparagraph.

Section 21. Food Contact with Equipment and Utensils.

(a) Food shall only contact surfaces of equipment and utensils that are cleaned as specified under Chapter 7, Section 1, of this Rule and sanitized as specified under Chapter 7, Section 15, of this Rule or single-service and single-use articles.

Section 22. Segregation and Location of Distressed Merchandise.

(a) Products that are held by the license holder for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single-service and single-use articles.

Section 23. Miscellaneous Sources of Contamination.

(a) Food shall be protected from contamination that may result from a factor or source not specified under Chapter 3, Sections 38 and 55.

Section 24. Linens and Napkins, Use Limitation.

(a) Linens and napkins may not be used in contact with food unless they are used to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new consumer.

Section 25. Food Storage, Allowable Areas.

(a) Except as specified in Chapter 3, Section 25(b) and (c), food shall be protected from contamination by storing the food:

(i) In a clean, dry location;

(ii) Where it is not exposed to splash, dust, or other contamination; and

(iii) At least six (6) inches (15 cm) above the floor.

(b) Food in packages and working containers may be stored less than six (6) inches (15 cm) above the floor on case lot handling equipment as specified under Chapter 6, Section 41.

(c) Pressurized beverage containers, cased food in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

Section 26. Food Storage, Prohibited Areas.

(a) Food may not be stored:

(i) In locker rooms;

(ii) In toilet rooms;

(iii) In dressing rooms;

(iv) In garbage rooms;

(v) In mechanical rooms;

(vi) Under sewer lines that are not shielded to intercept potential drips;

(vii) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

(viii) Under open stairwells; or

(ix) Under other sources of contamination.

Section 27. Storage or Display of Food in Contact with Water or Ice.

(a) Packaged food shall not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or it's positioning in the ice or water.

(b) Except as specified in Chapter 3, Section 27(c) and (d), unpackaged food may not be stored in direct contact with undrained ice.

(c) Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.

(d) Raw chicken and raw fish that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.

Section 28. Food Storage Containers, Identified with Common Name of Food.

(a) Working containers holding food or food ingredients that are removed from their original packages for use in the establishment, such as cooking oils, flour,

herbs, potato flakes, salt, spices, and sugar, shall be identified with the common name of the food except that containers holding food that can be readily and unmistakably recognized such as dry pasta need not be identified.

Section 29. Vended Potentially Hazardous Food, Original Container.

(a) Potentially hazardous food dispensed through a vending machine shall be in the package in which it was placed at the establishment or processing plant at which it was prepared.

Section 30. Cooling, Heating, and Holding Capacities.

(a) Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity to provide food temperatures as specified under Chapter 3, Sections 31, 41, 42, 43, 46, and 51.

Section 31. Cooling Times and Temperatures.

(a) Cooked potentially hazardous food shall be cooled:

(i) Within two (2) hours, from 135°F (60°C) to 70°F (21°C); and

(ii) Within four (4) hours from 70°F (21°C) to 41°F (5°C) or less.

(b) Potentially hazardous food shall be cooled within four (4) hours to 41°F (5°C) or less if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

(c) Except as specified in Chapter 3, Section 31(d), a potentially hazardous food received in compliance with laws allowing a temperature above 41°F (5°C) during shipment from the supplier as specified in Chapter 3, Section 19(b), shall be cooled within four (4) hours to 41°F (5°C) or less

(d) Raw eggs shall be received as specified under Chapter 3, Section 19(c) and immediately placed in refrigerated equipment that is capable of maintaining food at 41°F (5°C) or less.

Section 32. Cooling Methods.

(a) Cooling shall be accomplished in accordance with the time and temperature criteria specified under Chapter 3, Section 31, by using one or more of the

following methods based on the type of food being cooled:

(i) Placing the food in shallow pans;

(ii) Separating the food into smaller or thinner portions;

(iii) Using rapid cooling equipment;

(iv) Stirring the food in a container placed in an ice water bath;

(v) Using containers that facilitate heat transfer;

(vi) Adding ice as an ingredient; or

(vii) Other effective methods.

(b) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

(i) Arranged in the equipment to provide maximum heat transfer through the container walls; and

(ii) Loosely covered, or uncovered if protected from overhead contamination as specified under Chapter 3, Section 25 (a)(ii), during the cooling period to facilitate heat transfer from the surface of the food.

Section 33. Frozen Food Storage.

(a) Stored frozen foods shall be maintained frozen.

Section 34. Parasite Destruction in Fish.

(a) Except as specified in Chapter 3, Section 34 (b), before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish other than molluscan shellfish shall be frozen throughout to a temperature of:

(i) -4^{o}F (-20^{o}C) or below for a minimum of one hundred sixty eight (168) hours (7 days) in a freezer; or

(ii) -31^{o}F (-35^{o}C) or below until solid and stored at -31^{o}F (-35^{o}C) or below for a minimum of fifteen (15) hours or;

(iii) -31^{o}F (-35^{o}C) or below until solid and stored at -4^{o}F (-20^{o}C) or below

for a minimum of 24 hours.

(b) Chapter 3, Section 34 (a) does not apply to:

(i) Molluscan shellfish;

(ii) Tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern); or

(iii) Aquacultured fish, such as salmon, that:

(A) If raised in open water, are raised in net-pens, or

(B) Are raised in land-based operations such as ponds or tanks, and

(C) Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish.

(D) Fish eggs that have been removed from the skein and rinsed.

Section 35. Records, Creation and Retention for Freezing Fish.

(a) Except as specified in Chapter 3, Section 35(b), if raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the establishment for ninety (90) calendar days beyond the time of service or sale of the fish.

(b) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under Chapter 3, Section 34, may substitute for the records specified under Chapter 3, Section 35(a).

(c) If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, and the fish are raised and fed as specified in Chapter 3, Section 34 (b) (i), a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in Chapter 3, Section 34 (b) (i) shall be obtained by the person in charge and retained in the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish.

Section 36. Ice.

(a) Ice for use as a food or a cooling medium shall be made from drinking water.

Section 37. Ice Used as Exterior Coolant, Prohibited as Ingredient.

(a) After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice may not be used as food.

Section 38. Food Preparation Preventing Contamination.

(a) During preparation, unpackaged food shall be protected from environmental sources of contamination.

Section 39. Preventing Contamination from Hands.

(a) Food employees shall wash their hands as specified under Chapter 5.

(b) Except when washing fruits and vegetables as specified under Chapter 3, Section 40, or when otherwise approved, food employees shall minimize contact with exposed, ready-to-eat food with their bare hands through the use of suitable utensils such as deli tissue, spatulas, tongs, single-use gloves or dispensing equipment.

(c) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.

Section 40. Washing Fruits and Vegetables.

(a) Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form except as specified in Chapter 3, Section 40(b), and except that whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.

(b) Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 - Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

(c) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in an establishment or processing plant shall meet the requirements specified in 21 CFR 173.368 Ozone.

Section 41. Raw Animal Foods, Heating Times and Temperatures.

(a) Except as specified under Chapter 3, Section 41(b) and (c), raw animal foods, such as eggs, fish, meat, poultry and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

(i) 145°F (63°C) or above for 15 seconds for:

(A) Raw eggs that are broken and prepared in response to a consumer's order and for immediate service; and

(B) Except as specified under Chapter 3, Section 41(a)(ii) and (iii) and (b), fish and meat including game animals commercially raised for food as specified under Chapter 3, Section 4(a) and (b), and game animals under a voluntary inspection program as specified under Chapter 3, Section 4(c);

(ii) 155°F (68°C) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites, mechanically tenderized, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under Chapter 3, Section 4(a) and (b); game animals under a voluntary inspection program as specified under Chapter 3, Section 4(c); and raw eggs that are not prepared as specified under Chapter 3, Section 41(a)(i)(A):

(iii)

Minimum	
Temperature °F (°C)	**Time**
145 (63)	3 minutes
150 (66)	1 minute
158 (70)	<1 second (instantaneous)

or

(iv) 165°F (74°C) or above for 15 seconds for poultry, wild game animals as specified under Chapter 3, Section 4(b) and (c), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites or stuffing containing fish, meat, poultry or ratites.

(b) Whole meat roasts, including beef, corned beef, lamb, pork, and cured pork roasts such as ham, shall be cooked:

(i) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:

Oven Type	**Oven Temperature Based on Roast Weight**	
	Less than 10 lbs (4.5 kg)	10 lbs (4.5 kg)
Still Dry	350ºF (177ºC) or more	250ºF (121ºC) or more
Convection	325ºF (163ºC) or more	250ºF (121ºC) or more
High Humidity[1]	250ºF (121ºC) or more	250ºF (121ºC) or more
[1]Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity		

(ii) As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature:

Temperature ºF (ºC)	**Time[1] in Minutes**	**Temperature ºF (ºC)**	**Time[1] in Seconds**
130 (54.4)	112	146 (63.3)	169
131 (55.0)	89	147 (63.9)	134
132 (55.6)	71	148 (64.4)	107
133 (56.1)	56	149 (65.0)	85
134 (56.7)	45	150 (65.6)	67
135 (57.2)	36	151 (66.1)	54
136 (57.8)	28	152 (66.7)	43
137 (58.4)	23	153 (67.2)	34
138 (58.9)	18	154 (67.8)	27
139 (59.5)	15	155 (68.3)	22
140 (60.0)	12	156 (68.9)	17
141 (60.6)	9	157 (69.4)	14
142 (61.1)	8	158 (70.0)	0
143 (61.7)	6	159 (70.6)	0

144 (62.2)	5	160 (71.1)	0
145 (62.8)	4		
[1]*Holding time may include postoven heat rise.*			

(c) An undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:

(i) The establishment serves a population that is not a highly susceptible population;

(ii) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified under Chapter 3, Section 1(e); and

(iii) The steak is cooked on both the top and bottom to a surface temperature of 145ºF (63ºC) or above and a cooked color change is achieved on all external surfaces.

(d) A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in Chapter 3, Section 41(c), may be served or offered for sale in a ready-to-eat form if:

(i) The food establishment serves a population that is not a highly susceptible population;

(ii) The food, if served or offered for service by consumer selection from a children’s menu, shall not offer raw or undercooked comminuted meat; and

(iii) The food is prepared in response to a consumer’s order and for immediate service; or

(iv) The regulatory authority grants a variance from Chapter 3, Section 41 (a) or (b), as specified in Chapter 1, Section 5(a), based on a HACCP plan that:

(A) Is submitted by the license holder and approved a specified under Chapter 1, Section 6;

(B) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food; and

(C) Verifies that equipment and procedures for food preparation and training of food employees at the establishment meet the conditions of the variance.

Section 42. Raw Animal Food, Microwave Cooking.

(a) Raw animal food cooked in a microwave oven shall be:

(i) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(ii) Covered to retain surface moisture;

(iii) Heated to a temperature of at least 165°F (74°C) in all parts of the food; and

(iv) Allowed to stand covered for two (2) minutes after cooking to obtain temperature equilibrium.

Section 43. Plant Food Cooking for Hot Holding.

(a) Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 135ºF (57.2ºF).

Section 44. Non-Continuous Cooking of Raw Animal Foods.

(a) Raw animal foods that are cooked using a non-continuous cooking process shall be:

(i) Subject to an initial heating process that is no longer than sixty (60) minutes in duration;

(ii) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked potentially hazardous food (time /temperature control for safety food) under Chapter 3, Section 31(a);

(iii) After cooling, held frozen or cold, as specified for potentially hazardous food (time/temperature control for safety food) under Chapter 3, Section 51 (a)(ii);

(iv) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature of at least 165°F (74°C) for 15 seconds;

(v) Cooled according to the time and temperature parameters specified for cooked potentially hazardous food (time/temperature control for safety food) under Chapter 3, Section 31(a) if not either hot held as specified under Chapter 3, Section 51 (a)(i), served immediately, or held using time as a public health control as specified under

Chapter 3, Section 62 after complete cooking; and

(vi) Prepared and stored according to written procedures that:

(A) Have prior approval from the regulatory authority;

(B) Are maintained in the food establishment and are available to the regulatory authority upon request;

(C) Describe how the requirements specified under Chapter 3, Section 45 (a) (i)-(v) are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met;

(D) Describe how the foods, after initial heating but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under Chapter 3, Section 45 (a) (iv) prior to being offered for sale or service; and

(E) Describe how the foods, after initial heating but prior to cooking as specified under Chapter 3, Section 45 (a)(iv), are to be separated from ready-to-eat foods as specified under Chapter 3, Section 17.

Section 45. Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes.

(a) Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of foods such as caesar salad, hollandaise or Bearnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages that are not:

(i) Cooked as specified under Chapter 3, Section 41(a)(i) or (ii); or

(ii) Included in Chapter 3, Section 41(d).

Section 46. Reheating for Hot Holding.

(a) Except as specified under Chapter 3, Section 46 (b), (c), and (e), potentially hazardous food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165^{o}F (74^{o}C) for fifteen (15) seconds.

(b) Except as specified under Chapter 3, Section 46 (c), potentially hazardous food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165^{o}F (74^{o}C) and the food is rotated or stirred, covered, and allowed to stand covered for two (2) minutes after reheating.

(c) Ready-to-eat food taken from a commercially processed, hermetically sealed container, or from an intact package from a processing plant that is inspected by the regulatory authority shall be heated to a temperature of at least 135ºF (57.2ºF) for hot holding.

(d) Reheating for hot holding as specified in (a)-(c) of this Section shall be done rapidly and the time the food is between the temperature specified under Chapter 3, Section 51 (a)(ii), and as specified in (a)-(c) of this Section may not exceed two (2) hours.

(e) Remaining unsliced portions of meat roasts that are cooked as specified under Chapter 3, Section 41(b), may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under Chapter 3, Section 41(b).

Section 47. Reheating for Immediate Service.

(a) Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

Section 48. Food Temperature Measuring Devices.

(a) Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under Chapter 3.

(b) A temperature measuring device with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin foods such as meat patties and fish filets.

Section 49. Thawing Potentially Hazardous Foods.

(a) Except as specified in Chapter 3, Section 49 (a)(iv), potentially hazardous food shall be thawed:

(i) Under refrigeration that maintains the food temperature at 41°F (5^{o}C) or less); or

(ii) Completely submerged under running water:

(A) At a water temperature of 70°F (21^{o}C) or below;

(B) With sufficient water velocity to agitate and float off loose particles and overflow; and

(C) For a period of time that does not allow thawed portions of ready-to-eat food to rise above 41°F (5°C); or

(D) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under Chapter 3, Section 41(a) or (b), to be above 41°F (5°C) for more than four (4) hours including:

(I) The time the food is exposed to the running water and the time needed for preparation for cooking; or

(II) The time it takes under refrigeration to lower the food temperature to 41°F (5°C).

(iii) As part of a cooking process if the food that is frozen is:

(A) Cooked as specified under Chapter 3, Section 41(a) or (b), or Chapter 3, Section 42; or

(B) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or

(iv) Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

Section 50. Potentially Hazardous Food, Slacking.

(a) Frozen potentially hazardous food that is slacked to moderate the temperature shall be held:

(i) Under refrigeration that maintains the food temperature at 41°F (5°C) or less; or

(ii) At any temperature if the food remains frozen.

Section 51. Potentially Hazardous Food, Hot and Cold Holding.

(a) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under Chapter 3, Section 62, potentially hazardous food shall be maintained:

(i) At 135ºF (57.2ºC) or above, except that roasts cooked to a temperature and for a time specified under Chapter 3, Section 41(b), or reheated as specified in Chapter 3, Section 45(e), may be held at a temperature of 130°F (54°C) or above; or

(ii) At 41°F (5°C) or less.

(b) Eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of or less.

Section 52. Condiments, Protection.

(a) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.

(b) Condiments at a vending machine location shall be in packages or provided in dispensers that are filled at an approved location, such as the establishment that provides food to the vending machine location, a processing plant, or a properly equipped facility that is located on the site of the vending machine location.

Section 53. Utensils, Consumer Self-Service.

(a) A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar.

Section 54. Using Clean Tableware for Second Portions and Refills.

(a) Except for refilling a consumer's drinking cup or container without contact between the pouring utensil and the lip-contact area of the drinking cup or container, food employees may not use tableware, including single-service articles, soiled by the consumer, to provide second portions or refills.

(b) Except as specified in Chapter 3, Section 54 (c), self-service consumers may not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.

(c) Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified under Chapter 6, Section 30 (a)(i)(ii), and (iv).

Section 55. In-Use Utensils, Between-Use Storage.

(a) During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

(i) Except as specified under Chapter 3, Section 55 (a) (ii), in the food with their handles above the top of the food and the container;

(ii) In food that is not potentially hazardous with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;

(iii) On a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment is cleaned and sanitized at a frequency specified under Chapter 7, Sections 1 and 16;

(iv) In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

(v) In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous; or

(vi) In a container of water if the water is maintained at a temperature of at least 135ºF (57.2ºC) and the container is cleaned at a frequency specified under Chapter 7, Section 1(d) (vii).

Section 56. Refilling Returnables.

(a) A take-home food container returned to a food establishment may not be refilled at an establishment with a potentially hazardous food.

(b) Except as specified in Chapter 3, Section 56 (c), a take-home food container refilled with food that is not potentially hazardous shall be cleaned as specified under Chapter 7, Section 37(b).

(c) Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under Chapter 6, Section 30(a)(i), (ii) and (iv).

Section 57. Returned Food, Re-Service or Sale.

(a) Except as specified Chapter 3, Section 57 (b), after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption.

(b) Except as specified under Chapter 3, Section 69, a container of food that is not potentially hazardous may be transferred from one consumer to another if:

(i) The food is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

(ii) The food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.

Section 58. Food Display Protection.

(a) Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards, display cases; or other effective means.

Section 59. Consumer Self-Service Operations.

(a) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish may not be offered for consumer self-service. This paragraph does not apply to:

(i) Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;

(ii) Ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats, consumer-selected ingredients for Mongolian barbecue; or

(iii) Raw, frozen, shell-on shrimp or lobster.

(b) Consumer self-service operations for ready-to-eat foods shall provide suitable utensils or effective dispensing methods that protect the food from contamination.

(c) Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures.

Section 60. Ready-to-Eat, Potentially Hazardous Food, Date Marking.

(a) Except when packaging food using a reduced oxygen packaging method as specified in Chapter 3, Section 64, and except as specified in Chapter 3, Section 60 (d), refrigerated, ready-to-eat, potentially hazardous food prepared and held in an establishment for more than twenty four (24) hours shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature specified in Chapter 3, Section 51 (a) (ii) and the times noted below. The day of preparation shall be counted as Day 1.

(i) A maximum of seven (7) days at 41°F (5°C) or less

(b) Except as specified in Chapter 3, Section 60 (d) and (e), if the food is held for more than twenty four (24) hours refrigerated, ready-to-eat, potentially hazardous food prepared and packaged by a processing plant shall be clearly marked, at the time the original container is opened in an establishment to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in Chapter 3, Section 60 (a); and

(i) The day the original container is opened in the establishment shall be counted as Day 1; and

(ii) The day or date marked by the establishment may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety.

(c) A refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food) ingredient or a portion of a refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food) that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or first-prepared ingredient.

(d) A date marking system that meets the criteria stated in Chapter 3, Section 60 (a) and (b) may include:

(i) Using a method approved by the regulatory authority for refrigerated, ready-to-eat potentially hazardous food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;

(ii) Marking the date or day of preparation, with a procedure to discard the food or on before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified in (a) of this Section;

(iii) Marking the date or day the original container is opened in

a food establishment, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified in (b) of this Section; or

(iv) Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the regulatory authority upon request.

(e) Chapter 3, Section 60 (a) and (b), do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.

(f) Chapter 3, Section 60 (b) does not apply to the following foods prepared and packaged by a food processing plant inspected by a regulatory authority:

(i) Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR 110 Current good manufacturing practice in manufacturing, packing, or holding human food;

(ii) Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano*;*

(iii) Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;

(iv) Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;

(v) Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products defined in 21 CFR 114 Acidified foods;

(vi) Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami that are not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling, marking devices, and containers, and which retain the original casing on the product; and

(vii) Shelf stable salt-cured products such as prosciutto and Parma (ham) that are not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling, marking devices, and containers.

Section 61. Ready-to-Eat, Potentially Hazardous Food, Disposition.

(a) A food specified under Chapter 3, Section 60 (a) or (b), shall be

discarded if it:

(i) Is in a container or package that does not bear a date or day; or

(ii) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in Chapter 3, Section 51.

(b) Refrigerated, ready-to-eat, potentially hazardous food prepared in an establishment or processing plant and dispensed through a vending machine with an automatic shut-off control shall be discarded if it exceeds a temperature and time combination as specified in Chapter 3, Section 51.

Section 62. Time as a Public Health Control.

(a) Except as specified in Chapter 3, Section 62 (d), if time only, is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:

(i) Written procedures shall be prepared in advance, maintained in the establishment and made available to the regulatory authority upon request, that specify:

(A) Methods of compliance with Chapter 3, Section 61 (b) (i)-(iii) or (c) (i)-(v); and

(B) Methods of compliance with Chapter 3, Section 31 for food that is prepared, cooked, and refrigerated before time is used as a public health control.

(b) If time only, rather than time in conjunction with temperature control, up to a maximum of 4 hours, is used as the public health control:

(i) The food shall have an initial temperature of 41ºF (5ºC) or less if removed from cold holding temperature control or 135ºF (57ºC) or greater if removed from hot holding temperature control:

(ii) The food shall be marked or otherwise identified to indicate the time that is four (4) hours past the point in time when the food is removed from temperature control;

(iii) The food shall be cooked and served, served if ready-to-eat, or discarded within four (4) hours from the point in time when the food is removed from temperature control;

(iv) The food in unmarked containers or packages or marked to exceed

a four (4) hour limit shall be discarded.

(c) If time only, rather than time in conjunction with temperature control, up to a maximum of 6 hours, is used as the public health control:

(i) The food shall have an initial temperature of 41ºF (5ºC) or less when removed from temperature control and the food temperature may not exceed 70ºF (21ºC) within a maximum time period of 6 hours;

(ii) The food shall be monitored to ensure the warmest portion of the food does not exceed 70ºF (21ºC) during the 6-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 70ºF (21ºC) during the 6-hour holding period;

(iii) The food shall be marked or otherwise identified to indicate:

(A) The time when the food is removed from 41ºF (5ºC) or less cold holding temperature control, and

(B) The time that is 6 hours past the point in time when the food is removed from cold holding temperature control;

(iv) The food shall be:

(A) Discarded if the temperature of the food exceeds 70°F (21°C), or

(B) Cooked and served, served if ready-to-eat, or discarded within a maximum of 6 hours from the point in time when the food is removed from 41ºF (5ºC) or less cold holding temperature control; and

(v) The food in unmarked containers or packages, or marked with a time that exceeds the 6-hour limit shall be discarded.

(d) A food establishment that serves a highly susceptible population may not use time as specified in Chapter 3, Section 62 (a)-(c) as the public health control for raw eggs.

Section 63. Variance Requirement.

(a) An establishment or processing plant shall obtain a variance from the regulatory authority as specified in Chapter 1, Section 6, and under Chapter 1, Section 7, before:

(i) Smoking food as a method of food preservation rather than as a method of flavor enhancement;

(ii) Curing food;

(iii) Using food additives or adding components such as vinegar:

(A) As a method of food preservation rather than as a method of flavor enhancement, or

(B) To render a food so that it is not potentially hazardous;

(iv) Packaging food using a reduced oxygen packaging method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of Listeria monocytogenes are controlled as specified under Chapter 3, Section 64;

(v) Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;

(vi) Custom processing animals that are for personal use as food and not for sale or service in an establishment or processing plant;

(vii) Preparing food by another method that is determined by the regulatory authority to require a variance; or

(viii) Sprouting seeds or beans.

Section 64. Reduced Oxygen Packaging without a variance, Criteria.

(a) Except for an establishment or processing plant that obtains a variance as specified under Chapter 3, Section 63, an establishment or processing plant that packages potentially hazardous food using a reduced oxygen packaging method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*.

(b) An establishment or processing plant that packages potentially hazardous food using a reduced oxygen packaging method shall have a HACCP plan that contains the information specified under Chapter 10, Section 2(a)(iv), and that:

(i) Identifies the food to be packaged;

(ii) Except as specified in (c) and (e) and as specified in (d) of this Section, requires that the packaged food shall be maintained at 41ºF (5ºC) or less and meet at least one of the following criteria:

(A) Has an a_w of 0.91 or less;

(B) Has a pH of 4.6 or less;

(C) Is a meat or poultry product cured at a food processing plant regulated by the U.S.D.A. using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation and is received in an intact package; or

(D) Is a food with a high level of competing organisms such as raw meat, raw poultry or raw vegetables;

(iii) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(A) Maintain the food at 41ºF (5ºC) or below; and

(B) Discard the food if within fourteen (14) calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;

(iv) Limits the refrigerated shelf life to no more than fourteen (14) calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's “sell by" or "use by" date, whichever occurs first;

(v) Includes operational procedures that:

(A) Prohibit contacting ready-to-eat food with bare hands as specified under Chapter 3, Section 39 (b);

(B) Identify a designated area and the method by which:

(I) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination; and

(II) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation; and

(C) Delineate cleaning and sanitization procedures for food-contact surfaces; and

(vi) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(A) Concepts required for a safe operation;

(B) Equipment and facilities; and

(C) Procedures specified under Chapter 3, Section 64(a)(vi), and Chapter10, Section 2(a)(iv).

(c) Except for fish that is frozen before, during, and after packaging, an establishment may not package fish using a reduced oxygen packaging method.

(d) Except as specified in (c) of this Section, an establishment or processing plant that packages food using a cook-chill or sous vide process shall:

(i) Implement a HACCP plan that contains the information as specified in Chapter 10, Section 2 (iv);

(ii) Ensure the food is:

(A) Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer,

(B) Cooked to heat all parts of the food to a temperature and for a time as specified in Chapter 3, Section 41,

(C) Protected from contamination before and after cooking,

(D) Placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 135°F (57°C),

(E) Cooled to 41°F (5°C) in the sealed package as specified in Chapter 3, Section 31 and subsequently:

(I) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C); and held at that temperature until consumed or discarded within 30 days after the date of packaging;

(II) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C), removed from refrigeration equipment that maintains a 34°F (1°C) food temperature and then held at 41°F (5°C) or below for no more than 72 hours, at which time the food must be consumed or discarded.

(III) Cooled to 38°F (3ºC) or less within 24 hours of reaching 41ºF (5ºC) and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded; or

(IV) Held frozen with no shelf life restriction while frozen until consumed or used.

(F) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,

(G) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and

(H) Labeled with the product name and the date packaged; and

(iii) The records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan, are maintained and:

(A) Make such records available to the regulatory authority upon request, and

(B) Hold such records for at least 6 months; and

(iv) Implement written operational procedures as specified in (b) (v) of this Section and a training program as specified in (b) (vi) of this Section.

(e) An establishment that packages cheese using a reduced oxygen packaging method shall:

(i) Limit the cheeses packaged to those that are commercially manufactured in a processing plant with no ingredients added in the establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;

(ii) Have a HACCP plan that contains the information specified in Chapter 10, Section 2 (a) (iv) and as specified under (b)(i), (b)(iii)(A) and (b)(vi) of this Section;

(iii) Labels the package on the principal display panel with a “use by” date that does not exceed 30 days from its packaging or the original manufacturer’s “sell by” or “use by” date, whichever occurs first; and

(iv) Discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

Section 65. Standards of Identity, Date Information.

(a) Packaged food shall comply with standard of identity requirements as specified in law including the Wyoming Food, Drug and Cosmetic Safety Act, W. S. 35-7-110 through 35-7-127, 21 CFR 131-169 and 9 CFR 319 Definitions and Standards of Identity or Composition, and the general requirements in 21 CFR 130 - Food Standards: General and 9 CFR 319 Subpart A - General.

(b) Food establishment or manufacturers' dating information on foods may not be concealed or altered and must comply with law including the Wyoming Food, Drug and Cosmetic Safety Act, W. S. 35-7-110 through 35-7-127

Section 66. Honestly Presented.

(a) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer and as specified in law including the Wyoming Food, Drug and Cosmetic Safety Act, W. S. 35-7-110 through 35-7-127.

(b) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food and as specified in law including the Wyoming Food, Drug and Cosmetic Safety Act, W. S. 35-7-110 through 35-7-127.

Section 67. Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(a) Except as specified in Chapter 3, Section 41 (c) and (d) (iv) and in Chapter 3, Section 69 (a) (iii), if an animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens either in ready-to-eat form or as an ingredient in another ready-to-eat food, the license holder shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder, as specified in (b) and (c) of this section using brochures, deli case or menu advisories, label statements, table tents, placards or other effective written means.

(b) Disclosure shall include:

(i) A description of the animal-derived foods, such as “oysters on the half shell (raw oysters)” “raw-egg Caesar salad,” and “hamburgers (can be cooked to order)”; or

(ii) Identification of the animal-derived food by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may

contain) raw or undercooked ingredients.

(c) Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:

(i) Written information is available upon request regarding the safety of these items;

(ii) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of food borne illness; or

(iii) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of food borne illness, especially if you have certain medical conditions.

Section 68. Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

(a) A food that is unsafe, adulterated, or not honestly presented shall be reconditioned according to an approved procedure or discarded.

(b) Food that is not from an approved source as specified under Chapter 3, Sections 1-4 and 8-10, shall be discarded.

(c) Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under Chapter 1, Section 13, shall be discarded.

(d) Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded.

Section 69. Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

(a) In an establishment that serves a highly susceptible population:

(i) The following criteria apply to juice:

(A) For the purposes of this paragraph only, children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;

(B) Prepackaged juice or a prepackaged beverage containing

juice that bears a warning label as specified in 21 CFR, Section 101.17(g) Food Labeling, or a packaged juice or beverage containing juice, that bears a warning label as specified under Chapter 3, Section 76 (a) (ii) may not be served or offered for sale; and

(C) Unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form shall be processed under a HACCP plan that contains the information specified under Chapter 10, Section 2 (a)(ii)-(v) and as specified in 21 CFR Part 120 - Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls.

(ii) Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of:

(A) Foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages;

(B) Except as specified in Chapter 3, Section 69 (v), recipes in which more than one egg is broken and the eggs are combined;

(iii) The following foods may not be served or offered for sale in a ready-to-eat form:

(A) Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare;

(B) A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw eggs, and meringue; and

(C) Raw seed sprouts.

(iv) Time only, as the public health control as specified in Chapter 3, Section 62 (d), may not be used for raw eggs.

(v) Chapter 3, Section 69 (a) (ii)(B), does not apply if:

(A) The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified in Chapter 3, Section 41(a)(i), and served immediately, such as an omelet, soufflé, or scrambled eggs;

(B) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or

(C) The preparation of the food is conducted under a HACCP plan that:

(I) Identifies the food to be prepared;

(II) Prohibits contacting ready-to-eat food with bare hands;

(III) Includes specifications and practices that ensure:

(1.) *Salmonella enteritidis* growth is controlled before and after cooking; and

(2.) *Salmonella enteritidis* is destroyed by cooking the eggs according to the temperature and time specified in Chapter 3, Section 41(a)(ii);

(IV) Contains the information specified in Chapter 10, Section 2(a)(iv), including procedures that:

(1.) Control cross contamination of ready-to-eat food with raw eggs; and

(2.) Delineate cleaning and sanitization procedures for food-contact surfaces; and

(V) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

Section 70. Extraction of Honey.

(a) Honey should be extracted only from combs free from blood of the bees or the larvae of the wax moth, and combs that are properly capped.

(i) Combs from colonies containing dead adults or larvae, pesticides, antibiotics or any other adulterants shall not be extracted.

Section 71. Pumping Honey.

(a) Before pumping honey, it shall first be strained through a screen of at least eight mesh to the inch, or pumped from a baffled sump tank which provides a constant supply of honey for the pump.

Section 72. Honey Grading.

(a) All honey or honey product sold or offered for sale or grade shall conform to the grading requirements of 50 FR 15861 United States Standards for Grades of Extracted Honey or 32 FR 7565 United States Standards for Grades of Comb Honey for the specific grade to which reference is made.

Section 73. Meat and Poultry Establishment Processing Requirements.

(a) Meat and poultry products processed in an official establishment shall meet the requirements of 9 CFR 318 Products and Other Articles Entering Official Establishments, 319 Definitions and Standards of Identity or Composition, and 381 Poultry Products Inspection Regulations, Subpart O- Entry of Articles Into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements, and Subpart P- Definitions and Standards of Identity or Composition.

Section 74. Tagging Food Products, "Wyoming Retained."

(a) Any food product suspected of being adulterated or in any way unfit for human food may be tagged with a "Wyoming Retain" tag by the regulatory authority.

(i) The regulatory authority shall:

(A) Record the tag number; and

(B) The kind and amount of the food product retained.

(ii) The retain tag shall:

(A) Accompany the food product to the room in which it is retained for final inspection; and

(B) Not be removed except under the following condition:

(I) When the final inspection is made, if the food product is an inspected meat product the disposition shall be determined by the regulatory authority.

(iii) The regulatory authority shall make a complete record of the transaction.

(iv) If, upon final inspection, the food product is passed for food, the regulatory authority shall remove the retain tag and record the transaction.

(c) No meat food product which does not meet the requirements of the

Federal Meat Inspection Act, the Poultry Products Inspection Act, or 9 CFR 300 to End, may be prepared or sold.

(i) Any meat food product found to violate subsection (b) may be tagged with a "Wyoming Retain" tag by the regulatory authority;

(ii) The retained product shall not be sold or disposed of until an investigation is performed by the regulatory authority; and

(iii) The "Wyoming Retain" tag shall only be removed by the regulatory authority.

Section 75. Juice Treated.

(a) Pre-packaged juice shall:

(i) Be obtained from a processor with a HACCP system as specified in 21 CFR 120;

(ii) Be obtained pasteurized or otherwise treated to attain a 5-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR Part 120.24; or

(iii) Bear a warning label as specified in 21 CFR Section 101.17(g).

Section 76. Treating Juice.

(a) Juice packaged in an establishment or processing plant shall be:

(i) Treated under a HACCP plan as specified in Chapter 10, Section 2(a)(ii)-(v) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; or

(ii) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of pubic health significance:

(A) As specified under Chapter 4, and

(B) As specified in 21 CFR 101.17(g) with the phrase, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

CHAPTER 4

LABELING

Section 1. Labels.

(a) Food packaged in an establishment or processing plant shall be labeled as specified in law, including 21 CFR 101 Food Labeling and 9 CFR 317 Labeling, Marking Devices, and Containers.

(b) Label information shall include:

(i) The common name of the food, or absent a common name, an adequately descriptive identity statement;

(ii) If made from two (2) or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food;

(iii) An accurate declaration of the quantity of contents;

(iv) The name and place of business of the manufacturer, packer, or distributor;

(v) Except as exempted in the Federal Food, Drug, and Cosmetic Act 403(Q)(3)-(5) nutrition labeling as specified in 21 CFR 101 Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling;

(vi) For any salmonid fish containing canthaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin; and

(vii) The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient.

(c) Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:

(i) The manufacturer's or processor's label that was provided with the food; or

(ii) A card, sign, or other method of notification that includes the

information specified under Chapter 4, Section 1(b) (i), (ii), and (v).

(d) Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:

(i) A health, nutrient content, or other claim is not made;

(ii) There are no state or local laws requiring labeling; and

(iii) The food is manufactured or prepared on the premises of the establishment or processing plant or at another establishment or a processing plant that is owned by the same person and is regulated by the regulatory authority.

Section 2. Other Forms of Information.

(a) If required by law, consumer warnings shall be posted.

(b) Establishment, processing plant, or manufacturers' dating information on foods may not be concealed or altered.

Section 3. Country of Origin Food Labeling; Requirements and Inspections.

(a) Pursuant to 7 CFR 60 Country of Origin Labeling for Fish and Shellfish and 7 CFR 65 Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Macadamia Nuts, and Peanuts, every Perishable Agricultural Commodities Act (PACA) licensed retailer who sells or offers for sale in this state is required to notify customers of the country of origin of covered commodities.

(i) "Covered Commodities" include raw muscle cuts of beef (including veal), lamb, chicken, goat and pork; ground beef, lamb, pork, goat and chicken; wild and farm-raised fish and shellfish; perishable agricultural commodities; macadamia nuts, pecans, peanuts, and ginseng.

(A) Covered commodities are excluded from this part if the commodity is a processed food.

(ii) "Perishable agricultural commodity" means fresh and frozen fruits and vegetables of every kind and character which have not been manufactured into articles of a different kind or character, including cherries in brine.

(iii) "Processed food item" means a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity, or that has been combined with at least one (1) other covered

commodity or other substantive food component (e.g., chocolate, breading, sauces), except that the addition of a component (such as water, salt or sugar) would not in itself result in a processed food item. Specific processing that results in a change in the character of the covered commodity includes cooking, curing, smoking and restructuring.

(iv) "Retailer" as defined by the Perishable Agricultural Commodities Act (PACA) of 1930 refers only to retailers handling fresh and frozen fruits and vegetables with an invoice value of at least $230,000.00 annually. Those retailers are required to be licensed under PACA.

(v) "Wholesaler" any establishment that supplies retailers with one or more of the covered commodities and will be required by retailers to provide country of origin and, if applicable, method of production information so that the retailers can accurately supply that information to customers.

(b) The following labeling is required:

(i) Country of origin declarations which can be in the form of a placard, sign, label, sticker, band twist tie, pin tag, or other format which allows consumers to identify the country of origin.

(A) The declaration of the country of origin of a product may be in statement form such as “Product of the USA”, “Produce of the USA”, or “Grown in Mexico”, may state the country of origin only, such as USA or Canada; or may be indicated by a check box.

(B) The declaration of the country of origin must be legible and in a conspicuous location, which makes it likely to be read and understood by the customer under normal conditions of purchase.

(C) The declaration of country of origin may be typed, printed, or handwritten and must not obscure other labeling information.

(D) Bulk containers such as display cases, shipper containers, bins, cartons and barrels used at retail level to present product to consumers, may contain covered commodities from more than one country of origin provided all possible country of origins are listed.

(E) Only those country abbreviations approved for use under Customs and Border Protection rules, regulations and policies, such as “UK” for “The United Kingdom of Great Britain and Northern Ireland”, “Luxemb” for Luxembourg, and “U.S.” or “USA” for the “United States of America” are acceptable.

(I) Symbols or flags may be used to denote country of origin with or as part of a proper label.

(F) Domestic perishable agricultural commodities, peanuts, pecans, macadamia nuts and ginseng may use abbreviated U.S. state declarations as long as the federal Country Of Origin Labeling (COOL) regulations are followed and the official U.S. Postal Service abbreviations are used.

(G) Method of production for fish and shellfish can also be declared on the form described in Chapter 4, Section 3 (b) (i). Acceptable forms of production designations include, “wild caught”, “wild”, “farm-raised”, or “farmed”.

(I) Method of production designations of “ocean caught”, “caught at sea”, “line caught”, “cultivated”, or “cultured”, are not acceptable.

(c) The following record keeping is required:

(i) All records must be legible and may be maintained in either electronic or hard copy formats. Due to the variation in inventory and recordkeeping systems, various forms are acceptable.

(ii) Meat suppliers and retailers shall make records maintained in the normal course of business that verify an origin claim available to the director, upon request.

(A) Such records shall be provided within 5 business days of the request.

(iii) A supplier that provides a covered commodity to a retailer, whether directly or indirectly, must provide the country (ies) of origin information for covered commodities.

(iv) Country of origin labeling records, including pre-labeled consumer packages or master containers, must contain information identifying the retail supplier, the product, the country (ies) of origin and method of production (if applicable) tracking, linking the documentation to the covered commodity.

(A) Acceptable forms of tracking include:

(I) Invoices;

(II) Bills of lading; or

(III) Purchase orders; which must contain:

(1.) Purchase order number;

(2.) Date;

(3.) Product unique identifier, best by date, or lot number; and

(4.) Package size, brand name, etc.

(v) All records that identify a covered commodity shall be maintained for a period of one (1) year from the date the retailer makes the country of origin declaration.

(d) Inspectors of the Wyoming Department of Agriculture shall, as part of their routine evaluations of retail establishments, inspect the covered commodity declarations of country of origin and method of production, including the records maintained for covered commodities.

Section 4. Exemptions to Country of Origin Labeling.

(a) Exemptions to the country of origin labeling requirements are found in 7 CFR 65.140 Food Service Establishment and 7 CFR 65.220 Processed Food Item.

(b) Retailers not required to be PACA licensed are exempt from Section 3 above.

Section 5. Official Marks, Devices, Marking Products and Their Containers.

(a) The official inspection legend, marks, devices and certificates required by 9 CFR 312 Official Marks, Devices and Certificates, as amended, and 9 CFR 316 Marking Products and Their Containers, as amended, shall be applied and used on inspected and passed carcasses and parts of carcasses of cattle, sheep, swine and goats, meat food products in animal casings, and other products as approved by the director and shall be in the appropriate form.

(i) Meat inspection stamps which contain the words "Wyoming Inspected and Passed" and "Wyoming Inspected and Condemned" shall be provided by the Wyoming Department of Agriculture to all establishments which have been approved and granted state meat or poultry inspection service by the department.

(b) The use of the inspection legend is prohibited except under supervision of the director.

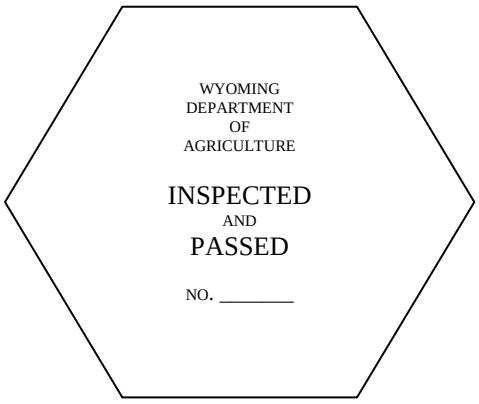
(i) No person shall affix or place or cause to be affixed or place the inspection legend, or any abbreviation, copy or representation thereof, to or on any product or container thereof except under the supervision of the director; and

(ii) No person shall fill or cause to be filled in whole or in part with any product, any container bearing or intended to bear the inspection legend or any abbreviation, copy or representation thereof, except under the supervision of the director.

(c) Brands and marking devices shall be approved by the director, and strict control of brands shall be maintained.

(i) The department shall furnish or have approved such ink brands, burning brands and like devices for marking products as the director may require.

(A) The mark of inspection on such a device shall be in the following form as a facsimile of one of the official brands using the size best suited for the purpose intended:



(ii) In advance of manufacture, brands and marking devices shall:

(A) Have complete and accurate descriptions and designs as specified in Chapter 4, Section 4(c) (i) (A), submitted to and approved by the director;

(B) Every such brand and device which bears the inspection legend shall be delivered into the custody of the Wyoming Department of Agriculture;

and

(C) Be used only under the supervision of the Wyoming Department of Agriculture;

(iii) When not in use for marking inspected and passed product, all such brands and devices bearing the inspection legend shall be kept locked in properly equipped lockers or compartments, the keys of which shall not leave the possession of the regulatory authority.

(d) No person shall remove or cause to be removed from an official establishment any article which this Rule requires to be marked.

(e) Branding ink shall be:

(i) Furnished by the official establishment for marking product;

(ii) Made with harmless ingredients that are approved by the Wyoming Department of Agriculture; and

(iii) Of proper color.

(f) Brands or marking devices shall be of such style and type as will make a clear and legible impression as determined by the Wyoming Department of Agriculture.

(g) Each carcass which has been inspected and passed in an official establishment shall be marked at the time of inspection with the inspection legend in accordance with 9 CFR 316 Marking Products and Their Containers and 9 CFR 381, Subpart M-Official Marks, Devices and Certificates; Export Certificates; Certification Procedures.

(h) The official inspection legend, marks, devices and certificates required by 9 CFR 352 Exotic Animals; Voluntary Inspection or 9 CFR 354 Voluntary Inspection of Rabbits and Edible Products Thereof shall be applied and used on inspected and passed carcasses and parts of carcasses of exotic animals or rabbits as approved by the director and shall be in the appropriate form.

(i) The specific requirements for use of an official mark of inspection shall be the same as Section 5 (a)-(g) above and Section 6 below.

Section 6. Specific Labeling Requirements for Inspected and Passed Meat and Poultry Products, Label Contents and Approval.

(a) Any inspected and passed meat or poultry product placed or packed in any

can, pot, tin, canvas or other receptacle or covering constituting an immediate or true container shall be labeled as specified in this Rule, or in law, including 9 CFR 317 Labeling, Marking Devices and Containers and 9 CFR 381, Subpart N-Labeling and Containers.

(b) Labels shall be approved by the director.

(i) No label shall be used on any product until it has been approved in its final form by the director.

(A) The label shall be submitted in triplicate to the director for approval; and

(B) The label shall be submitted as it appears in its final form.

(ii) Inserts, tags, liners, posters and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be:

(A) Submitted for approval in the same manner as provided for labels in Chapter 4, Section 6 (b) (i), except that:

(I) Inspectors may permit use of such devices which contain no reference to product and bear no misleading feature.

(iii) The inspector may permit the use of approved labels or other marking modifications provided the labeling or marking as modified is so used as not to be false or deceptive.

(iv) Approved labels shall only be used on:

(A) Products to which they are applicable; and

(B) Products for which they are approved.

Section 7. Ungraded Eggs.

(a) A person selling ungraded eggs in Wyoming shall follow the requirements for an exempt producer as defined in 7 CFR 57, Inspection of Eggs (Egg Products Inspection Act).

(b) Any person selling ungraded, uninspected eggs in Wyoming shall:

(i) Label the carton:

(A) Ungraded eggs;

(B) Include the name and address of the exempt producer; and

(C) Include a packing date and the statement “Keep Refrigerated.”

(c) Reuse of cartons:

(i) Only cartons that are clean and in good condition may be reused;

(ii) Cartons with a USDA Grade shield shall not be reused; and

(iii) All wording and dates on reused cartons shall be completely marked out.

Section 8. Bottled Water Labeling Requirements.

(a) All bottled water shall conform to 21 CFR 101 Food Labeling and be labeled in compliance with the following standards:

(i) Mineral water may be labeled "mineral water," or "natural mineral water."

(ii) Spring water may be labeled "spring water" or "natural spring water."

(iii) Water containing carbon dioxide that emerges from the source and is bottled directly with its entrapped gas or from which the gas is naturally occurring in the water may bear on its label the words "naturally carbonated" or "naturally sparkling."

(iv) Bottled water which contains carbon dioxide other than that which is naturally occurring in the source of the product shall be labeled with the words "carbonated" or "sparkling" when the carbonation is obtained from a natural or manufactured source.

(v) Well water may be labeled "well water" or "natural well water."

(vi) Artesian water may be labeled "artesian water," "natural artesian water," "well water" or "natural well water."

(vii) Purified water shall be labeled "purified water" and the method of preparation shall be stated on the label. However, nothing contained herein shall preclude

labeling purified water produced by distillation as "distilled water."

(viii) Drinking water may be labeled "drinking water."

(ix) Any bottler, distributor or vendor of bottled water whose corporate name, brand name or trademark contains the words "spring," "springs," "well," "artesian well," "mineral" or "natural" or any derivative of those words shall label each bottle with the source of the water in type face at least equal to the size of the type face of the corporate name or trademark, if the source of the bottled water is different from the source stated in the corporate name, brand name or trademark.

(x) The use of words "spring," "spring fresh," "spring brand," "spring type," or other language containing the word "spring" to describe water that is not spring water as defined herein shall be prohibited.

(xi) A product meeting more than one definition may be identified by any of the applicable product names, except where otherwise specifically prohibited.

(xii) Supplemental printed information and graphics concerning recognized uses of the water may appear on the label but shall not imply properties of the product or preparation methods which are not factual.

CHAPTER 5

PERSONAL HYGIENE

Section 1. Employee Health.

(a) Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

Section 2. Clean Condition.

(a) Food employees shall keep their hands and exposed portions of their arms clean.

Section 3. Cleaning Procedure.

(a) Except as specified in Chapter 5, Section 3 (d), food employees shall clean their hands and exposed portions of their arms (or surrogate prosthetic devices for hands or arms) for at least 20 seconds, using a cleaning compound in a lavatory that is equipped as specified under Chapter 8, Section 55(a)

(b) Food employees shall use the following cleaning procedure:

(i) Administering vigorous friction on the surfaces of the lathered fingers, finger tips, areas between the fingers, hands and arms (or by vigorously rubbing the surrogate prosthetic devices for hands or arms) for at least 10 to 15 seconds, followed by;

(ii) Thorough rinsing under clean, running warm water; and

(iii) Immediately follow the cleaning procedure with thorough drying of cleaned hands and arms (or surrogate prosthetic devices) using a method as specified in Chapter 8, Section 58.

(c) Food employees shall pay particular attention to the areas underneath the fingernails during the cleaning procedure.

(d) An automatic handwashing facility, capable of removing the types of soils encountered in the food operations involved and approved by the Department, may be used by food employees to clean their hands or surrogate prosthetic devices.

Section 4. When To Wash.

(a) Food employees shall clean their hands and exposed portions of their arms as specified under Chapter 5, Section 3, immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles and:

(i) After touching bare human body parts other than clean hands and clean, exposed portions of arms;

(ii) After using the toilet room;

(iii) After caring for or handling service animals or aquatic animals as specified in Chapter 5, Section 9(e);

(iv) Except as specified in Chapter 5, Section 9 (b) (i), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;

(v) After handling soiled equipment or utensils;

(vi) During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;

(vii) When switching between working with raw food and working with ready-to-eat food;

(viii) Before donning gloves for working with food;

(ix) After dressing or handling diseased carcasses, inedibles, viscera, or paunches; and

(x) After engaging in other activities that contaminate the hands.

Section 5. Where To Wash.

(a) Food employees shall clean their hands in a handwashing sink or approved automatic handwashing facility and may not clean their hands in a sink used for food preparation or warewashing, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.

Section 6. Hand Antiseptics.

(a) A hand antiseptic used as a topical application, a hand antiseptic solution

used as a hand dip, or a hand antiseptic soap shall:

(i) Comply with one of the following:

(A) Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness; or

(B) Have active antimicrobial ingredients that are listed in:

(I) The FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash; and

(ii) Comply with one of the following:

(A) Have components that are exempted from the requirement of being listed in federal Food Additive regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles; or

(B) Comply with and be listed in:

(I) 21 CFR 178- Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as an additive with conditions of safe use; or

(II) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food; and

(iii) Be applied only to hands that are cleaned as specified under Chapter 5, Section 3.

(b) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Chapter 5, Section 6(a), use shall be:

(i) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or

(ii) Limited to situations that involve no direct contact with food by the bare hands.

(c) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least one hundred (100) mg/l chlorine.

Section 7. Gloves, Use Limitation.

(a) If used, single-use gloves shall be used for only one task such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

(b) Except as specified in Chapter 5, Section 7(c), slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under Chapter 3, Section 41, such as frozen food or a primal cut of meat.

(c) Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.

(d) Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under Chapter 3, Section 41, such as frozen food or a primal cut of meat.

Section 8. Clothing.

(a) Food employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

(b) Except as provided in Chapter 5, Section 8(c), food employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair that are designed and worn to effectively keep their hair from contacting exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(c) This Section does not apply to food employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses, and wait staff if they present a minimal risk of contaminating exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

Section 9. Employee Practices.

(a) Except as specified in Chapter 5, Section 9(b), an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection cannot result.

(b) A food employee may drink from a closed beverage container if the container is handled to prevent contamination of:

(i) The employee's hands;

(ii) The container; and

(iii) Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(c) While preparing food, food employees may not wear jewelry on their arms or hands. This Section does not apply to a plain ring such as a wedding band.

(d) Except as specified in Chapter 5, Section 9 (e), food employees may not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed as specified in Chapter 9, Section 52 (b)(ii)-(iv).

(e) Food employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified under Chapter 5, Sections 3 and 4 (a) (iii).

(f) Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.

(g) Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails when working with exposed food.

CHAPTER 6

EQUIPMENT AND UTENSILS

Section 1. Equipment and Utensils, Design and Construction.

(a) Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under conditions of normal use.

Section 2. Lead in Ceramic, China, and Crystal Utensils; Use Limitation.

(a) Ceramic, china, crystal utensils, and decorative utensils such as hand painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:

Utensil Category	Ceramic Article Description	Maximum Lead mg/l
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls 1.1 L (1.16 qt)	1
Small Hollowware (excluding cups & mugs)	Bowls < 1.1 L (1.16 qt)	2.0
Flat Tableware	Plates, Saucers	3.0

(b) Pewter alloys containing lead in excess of 0.05% may not be used as a food contact surface.

(c) Solder and flux containing lead in excess of 0.2% may not be used as a food contact surface.

Section 3. Copper, Use Limitation.

(a) Except as specified in Chapter 6, Section 3(b), copper and copper alloys such as brass may not be used in contact with a food that has a pH below 6 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.

(b) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the pre-fermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

Section 4. Galvanized Metal, Use Limitation.

(a) Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.

Section 5. Single-Service and Single-Use.

(a) Materials that are used to make single-service and single-use articles:

(i) May not:

(A) Allow the migration of deleterious substances; or

(B) Impart odors, colors, or tastes to food; and

(ii) Shall be:

(A) Safe; and

(B) Clean.

Section 6. Wood, Plastic; Use Limitation.

(a) Except as specified in Chapter 6, Section 6 (b), (c), and (d), wood and wood wicker may not be used as a food-contact surface.

(b) Hard maple or an equivalently hard, close-grained wood may be used for:

(i) Cutting blocks; cutting boards; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and

(ii) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 230°F (110°C) or above.

(c) Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.

(d) If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:

(i) Untreated wood containers; or

(ii) Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for wood.

(e) Safe plastic or safe rubber or safe rubber-like materials that are resistant under normal conditions of use to scratching, scoring, decomposition, crazing, chipping and distortion, that are of sufficient weight and thickness to permit cleaning and sanitizing by normal dishwashing methods may be used.

Section 7. Shells, Use Limitation.

(a) Mollusk and crustacea shells may not be used more than once as serving containers.

Section 8. Single-Service and Single-Use Articles, Use Limitation.

(a) Single service and single-use articles may not be reused.

(b) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one (1) inch (2.5 cm) protruding from the chilled dispensing head.

Section 9. Single-Service and Single-Use Articles, Required Use.

(a) An establishment without facilities specified under Chapter 7, Sections 1 and 2, for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.

Section 10. Food Equipment, Certification and Classification.

(a) Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Sections 1 and 11, of this Chapter.

Section 11. Characteristics of Food Contact Surfaces.

(a) Materials that are used in the construction of utensils, and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food under conditions of normal use and shall be:

(i) Safe;

(ii) Durable, corrosion-resistant, and nonabsorbent;

(iii) Sufficient in weight and thickness to withstand repeated warewashing;

(iv) Finished to have a smooth, easily cleanable surface; and

(v) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

Section 12. Conditioning Device, Design.

(a) A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

Section 13. Nonstick Coatings, Use Limitation.

(a) Multi-use kitchenware such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with non-scoring or non-scratching utensils and cleaning aids.

Section 14. Food-Contact Surfaces.

(a) Multi-use food-contact surfaces shall be:

(i) Smooth;

(ii) Free of breaks, open seams, cracks, chips, pits, and similar imperfections;

(iii) Free of sharp internal angles, corners and crevices;

(iv) Finished to have smooth welds and joints; and

(v) Accessible for cleaning and inspection by one of the following

methods:

(A) Without being disassembled;

(B) By disassembling without the use of tools; or

(C) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and allen wrenches.

Section 15. Cast Iron, Use Limitation.

(a) Except as specified in Chapter 6, Section 15(b) and (c), cast iron may not be used for utensils or food-contact surfaces of equipment.

(b) Cast iron may be used as a surface for cooking.

(c) Cast iron may be used in utensils for serving food if the utensils are used only as part of an uninterrupted process from cooking through service.

Section 16. "V" Threads, Use Limitation.

(a) "V" type threads may not be used on food-contact surfaces. This Section does not apply to hot oil cooking equipment or filtering equipment.

Section 17. Hot Oil Filtering Equipment.

(a) Hot oil filtering equipment shall meet the characteristics specified under Chapter 6, Sections 14 and 33, and shall be readily accessible for filter replacement and cleaning of the filter.

Section 18. Molluscan Shellfish Tanks.

(a) Except as specified under Chapter 6, Section 18(b), molluscan shellfish life support system display tanks may not be used to store or display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only.

(b) Molluscan shellfish life-support system display tanks that are used to store or display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified

in Chapter 1, Section 5, and a HACCP Plan that:

(i) Is submitted by the license holder and approved as specified under Chapter 1, Section 6; and

(ii) Ensures that:

(A) Water used with fish other than molluscan shellfish does not flow into the molluscan tank;

(B) The safety and quality of the shellfish as they were received are not compromised by the use of the tank; and

(C) The identity of the source of the shellstock is retained as specified under Chapter 3, Section 15.

Section 19. Can Openers.

(a) Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

Section 20. Can Openers on Vending Machines.

(a) Cutting or piercing parts of can openers on vending machines shall be protected from manual contact, dust, insects, rodents, and other contamination.

Section 21. Equipment Openings, Closures and Deflectors.

(a) A cover or lid for equipment shall overlap the opening and be sloped to drain.

(b) An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least two-tenths (.2) of an inch (5 millimeters).

(c) Except as specified under Chapter 6, Section 21(d), fixed piping, temperature measuring devices, rotary shafts, and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.

(d) If a watertight joint is not provided:

(i) The piping, temperature measuring devices, rotary shafts, and other

parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the food; and

(ii) The opening shall be flanged as specified under Chapter 6, Section 21(b).

Section 22. Vending Machine, Vending Stage Closure.

(a) The dispensing compartment of a vending machine including a machine that is designed to vend prepackaged snack food that is not potentially hazardous such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

(i) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(ii) Available for self-service during hours when it is not under the full-time supervision of a food employee.

Section 23. Vending Machines, Automatic Shutoff.

(a) A machine vending potentially hazardous food shall have an automatic control that prevents the machine from vending food:

(i) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that cannot maintain food temperatures as specified under Chapter 3, Section 50; and

(ii) If a condition specified under Chapter 6, Section 23(a)(i), occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified under Chapter 3, Section 50.

(b) When the automatic shutoff within a machine vending potentially hazardous food is activated:

(i) In a refrigerated vending machine, the ambient temperature may not exceed 41^{o}F (5^{o}C) or 45^{o}F (7^{o}C) as specified under Chapter 3, Section 50(a)(iii), for more than thirty (30) minutes immediately after the machine is filled, serviced, or restocked; or

(ii) In a hot holding vending machine, the ambient temperature may not be less than 135ºF (57.2ºF) for more than one hundred twenty (120) minutes

immediately after the machine is filled, serviced, or restocked.

Section 24. Vending Machine Doors and Openings.

(a) Vending machine doors and access opening covers to food and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than one-sixteenth (1/16) inch (1.5 millimeters) or by:

(i) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than one-sixteenth (1/16) inch or (1.5 millimeters). Screening of twelve (12) or more mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement;

(ii) Being effectively gasketed;

(iii) Having interface surfaces that are at least one-half (2) inch (13 millimeters) wide; or

(iv) Jambs or surfaces used to form an L-shaped entry path to the interface.

(b) Vending machine service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than one-sixteenth (1/16) inch or (1.5 millimeters).

Section 25. Bearings and Gear Boxes, Leakproof.

(a) Equipment containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant cannot leak, drip, or be forced into food or onto food-contact surfaces.

Section 26. Food-Contact Surface Lubricants.

(a) Lubricants shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.

Section 27. Condenser Unit, Separation.

(a) If a condenser unit is an integral component of equipment, the condenser unit shall be separated from the food and food storage space by a dust proof barrier.

Section 28. Dispensing Equipment, Protection of Equipment and Food.

(a) In equipment that dispenses or vends liquid food or ice in unpackaged form:

(i) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food;

(ii) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

(iii) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:

(A) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) Available for self-service during hours when it is not under the full-time supervision of a food employee; and

(iv) The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

Section 29. Beverage Tubing, Separation.

(a) Beverage tubing and cold-plate beverage cooling devices may not be installed in contact with stored ice. This Section does not apply to cold plates that are constructed integrally with an ice storage bin.

Section 30. Ice Units, Separation of Drains.

(a) Liquid waste drain lines may not pass through an ice machine or ice storage bin.

Section 31. Warewashing Sinks and Drainboards, Self-Draining.

(a) Sinks and drainboards of warewashing sinks and machines shall be self-draining.

Section 32. Equipment Compartments, Drainage.

(a) Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

Section 33. CIP Equipment.

(a) CIP equipment shall meet the characteristics specified under Chapter 6, Section 14, and shall be designed and constructed so that:

(i) Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces; and

(ii) The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.

(b) CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

Section 34. Vending Machines, Liquid Waste Products.

(a) Vending machines designed to store beverages that are packaged in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(b) Vending machines that dispense liquid food in bulk shall be:

(i) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and

(ii) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(c) Shutoff devices specified under Chapter 6, Section 34(b)(ii), shall prevent water or liquid food from continuously running if there is a failure of a flow control device in the water or liquid food system or waste accumulation that could lead to overflow of the waste receptacle.

Section 35. Temperature Measuring Devices.

(a) In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

(b) Except as specified in Chapter 6, Section 35(c), cold or hot holding equipment used for potentially hazardous food shall be designed to include and shall be equipped with at least one integral or permanently affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.

(c) Chapter 6, Section 35(b), does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.

(d) Temperature measuring devices shall be designed to be easily readable.

(e) Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than $2^{o}F$ or $1^{o}C$ in the intended range of use.

Section 36. Food Temperature Measuring Devices.

(a) Food temperature measuring devices may not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.

(b) Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to $\pm 1^{\circ}C$ in the intended range of use.

(c) Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to $\pm 2^{o}F$ in the intended range of use.

Section 37. Temperature Measuring Devices, Ambient Air and Water.

(a) Ambient air and water temperature measuring devices that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to $1.5^{\circ}C$ in the intended range of use.

(b) Ambient air and water temperature measuring devices that are scaled only in Fahrenheit shall be accurate to 3°F in the intended range of use.

Section 38. Pressure Measuring Devices, Mechanical Warewashing Equipment.

(a) Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of seven (7) kilopascals (1 pound per square inch) or smaller and shall be accurate to 14 kilopascals (2 pounds per square inch) in the 100-170 kilopascals (15-25 pounds per square inch) range.

Section 39. Nonfood-Contact Surfaces.

(a) Nonfood-contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent, and smooth material.

(b) Nonfood-contact surfaces shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

Section 40. Kick Plates, Removable.

(a) Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(i) Removable by one of the methods specified under Chapter 6, Section 14 (a)(v)(A) - (C), or capable of being rotated open; and

(ii) Removable or capable of being rotated open without unlocking equipment doors.

Section 41. Case Lot Handling Apparatuses, Movability.

(a) Apparatuses, such as dollies, pallets, racks, and skids used to store and transport large quantities of packaged foods received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available equipment such as hand trucks and forklifts.

Section 42. Heating, Ventilating, Air Conditioning System Vents.

(a) Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment, or utensils.

Section 43. Ventilation Hood Systems, Drip Prevention.

(a) Exhaust ventilation hood systems in food preparation and warewashing areas including components such as hoods, fans, guards, and ducts shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.

Section 44. Ventilation Hood Systems, Filters.

(a) Filters or other grease extracting equipment shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

Section 45. Equipment Repair and Proper Adjustment.

(a) Equipment shall be maintained in a state of repair and condition that meets the requirements specified under Chapter 6, Sections 1 and 11.

(b) Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

(c) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

Section 46. Utensil Repair and Calibration.

(a) Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under Chapter 6, Sections 1 and 11, or shall be discarded.

(b) Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

(c) Ambient air temperature, water pressure, and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use.

Section 47. Cutting Surfaces.

(a) Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced.

Section 48. Microwave Ovens.

(a) Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.

Section 49. Fixed Equipment, Elevation or Sealing.

(a) Except as specified under Chapter 6, Section 49(b) and (c), floor-mounted equipment that is not easily movable shall be sealed to the floor or on legs that provide at least a six (6) inch (15 centimeter) clearance between the floor and the equipment.

(b) If no part of the floor under the floor-mounted equipment is more than six (6) inches (15 centimeters) from the point of cleaning access, the clearance space may be only four (4) inches (10 centimeters).

(c) This Section does not apply to display shelving units, display refrigeration units, and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.

(d) Except as specified under Chapter 6, Section 49(e), counter-mounted equipment that is not easily movable shall be elevated on legs that provide at least a four (4) inch (10 centimeter) clearance between the table and the equipment.

(e) The clearance space between the table and counter-mounted equipment may be:

(i) Three (3) inches (7.5 centimeters) if the horizontal distance of the table top under the equipment is no more than twenty (20) inches (50 centimeters) from the point of access for cleaning; or

(ii) Two (2) inches (5 centimeters) if the horizontal distance of the table top under the equipment is no more than three (3) inches (7.5 centimeters) from the point of access for cleaning.

Section 50. Fixed Equipment, Spacing or Sealing.

(a) Equipment that is fixed because it is not easily movable shall be installed so that it is:

(i) Spaced to allow access for cleaning along the sides, behind, and above the equipment;

(ii) Spaced from adjoining equipment walls, and ceilings a distance of not more than one thirty-second (1/32) inch or 1 millimeter; or

(iii) Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

(b) Counter-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:

(i) Sealed; or

(ii) Elevated on legs as specified under Section Chapter 6, Section 49(d).

CHAPTER 7

CLEANING, SANITIZATION AND STORAGE OF EQUIPMENT AND UTENSILS

Section 1. Equipment Food-Contact Surfaces and Utensils.

(a) Equipment food-contact surfaces and utensils shall be cleaned:

(i) Except as specified in Chapter 7, Section 1(b), between each use of a different type of raw animal species such as beef, fish, lamb, pork, or poultry;

(ii) Each time there is a change from working with raw food to working with ready-to-eat food;

(iii) Between uses with raw fruits and vegetables and potentially hazardous food;

(iv) Before using or storing a food temperature measuring device; and

(v) At any time during the operation when contamination may have occurred.

(b) Chapter 7, Section 1(a)(i), does not apply if raw animal foods that require cooking temperatures specified under Chapter 3, Section 41(a)(iii), are prepared after foods that require cooking temperatures specified under Chapter 3, Section 41(a)(i) and (ii) and b.

(c) Except as specified in Chapter 7, Section 1(d), if used with potentially hazardous food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every four (4) hours.

(d) Surfaces of utensils and equipment contacting potentially hazardous food may be cleaned less frequently than every four (4) hours if:

(i) In storage, containers of potentially hazardous food and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;

(ii) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart: and

(A) The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature:

Temperature	Cleaning Frequency
41ºF (5.0ºC) or less	24 hours
>41ºF - 45ºF (>5.0ºC - 7.2ºC)	20 hours
>45ºF - 50ºF (>7.2ºC - 10.0ºC)	16 hours
>50ºF - 55ºF (>10.0ºC - 12.8º C)	10 hours

and

(B) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the establishment or processing plant;

(iii) Containers in serving situations, such as salad bars, delis, and cafeteria lines that hold ready-to-eat potentially hazardous food that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every twenty four (24) hours;

(iv) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Chapter 3;

(v) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;

(vi) The cleaning schedule is approved based on consideration of:

(A) Characteristics of the equipment and its use;

(B) The type of food involved;

(C) The amount of food residue accumulation; and

(D) The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease;

(vii) In-use utensils are intermittently stored in a container of water in which the water is maintained at 135ºF (60ºC) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(e) Except when dry cleaning methods are used as specified under Chapter 7, Section 4, surfaces of utensils and equipment contacting food that is not potentially hazardous shall be cleaned:

(i) At any time when contamination may have occurred;

(ii) At least every twenty four (24) hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles; or

(iii) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers;

(f) Equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, beverage dispensing lines or tubes, coffee bean grinders, and water vending equipment shall be cleaned:

(i) At a frequency specified by the manufacturer; or

(ii) At a frequency necessary to preclude accumulation of soil or mold in the absence of manufacturer specifications.

Section 2. Cooking and Baking Equipment.

(a) The food-contact surfaces of cooking and baking equipment shall be cleaned at least every twenty four (24) hours. This Section does not apply to hot oil cooking and filtering equipment if it is cleaned as specified under Chapter 7, Section 1(d)(vi).

(b) The cavities and door seals of microwave ovens shall be cleaned at least every twenty four (24) hours by using the manufacturer's recommended cleaning procedure.

(c) Equipment food-contact surfaces and utensils shall be clean to sight and touch.

(d) The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.

Section 3. Nonfood-Contact Surfaces.

(a) Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

(b) Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.

Section 4. Dry Cleaning Methods.

(a) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not potentially hazardous.

(b) Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose.

Section 5. Wiping Cloths Used for One Purpose.

(a) Cloths used for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:

(i) Maintained dry; and

(ii) Used for no other purpose.

(b) Cloths used for wiping counters and other equipment surfaces shall be:

(i) Held between uses in a chemical sanitizer solution at a concentration specified in Chapter 7, Section 18; and

(ii) Laundered daily as specified Chapter 9, Section 47 (d).

(c) Cloths used for wiping surfaces in contact with raw animal foods shall be kept separate from cloths used for other purposes.

(d) Dry wiping cloths and the chemical sanitizing solutions specified in (b) (i) of this Section in which wet wiping cloths are held between uses shall be free of food debris and visible soil.

(e) Containers of chemical sanitizing solutions specified in (b)(i) of this Section in which wet wiping cloths are held between uses shall be stored off the floor and

used in a manner that prevents contamination of food, equipment, utensils, linens, single-service, or single-use articles.

(f) Single-use disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer’s label use instructions.

Section 6. Sponges, Use Limitation.

(a) Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces.

Section 7. Manual Warewashing, Sink Compartment Requirements.

(a) Except as specified in Chapter 7, Section 7(c), a sink with at least three (3) compartments shall be provided for manual washing, rinsing and sanitizing equipment and utensils.

(b) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink or a warewashing machine, alternative equipment as specified in Chapter 7, Section 7(c), shall be used.

(c) Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:

(i) High-pressure detergent sprayers;

(ii) Low- or line-pressure spray detergent foamers;

(iii) Other task-specific cleaning equipment;

(iv) Brushes or other implements;

(v) Two (2)-compartment sinks as specified under Chapter 7, Section 7(d) and (e); or

(vi) Receptacles that substitute for the compartments of a multicompartment sink.

(d) Before a two (2)-compartment sink is used:

(i) The license holder shall have its use approved; and

(ii) The permit holder shall limit the number of kitchenware items cleaned and sanitized in the 2-compartment sink, and shall limit warewashing to batch operations for cleaning kitchenware such as between cutting one type of raw meat and another or cleanup at the end of a shift, and shall:

(A) Make up the cleaning and sanitizing solutions immediately

before use and drain them immediately after use, and

(A) Use a detergent-sanitizer to sanitize and apply the detergent-sanitizer in accordance with the manufacturer's label instructions and as specified under Chapter 7, Section 20; or

(B) Use a hot water sanitization immersion step as specified under Chapter 7, Section 22(a)(ii).

(e) A two (2)-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.

Section 8. Washing, Procedures for Alternative Manual Warewashing Equipment.

(a) If washing in sink compartments or a warewashing machine is impractical such as when the equipment is fixed or the utensils are too large, washing shall be done by using alternative manual warewashing equipment as specified under Chapter 7, Section 7(c), in accordance with the following procedures:

(i) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts;

(ii) Equipment components and utensils shall be scraped or rough cleaned to remove food particle accumulation; and

(iii) Equipment and utensils shall be washed as specified under Chapter 7, Section 11(a).

Section 9. Drainboards Provided.

(a) Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing.

Section 10. Warewashing Equipment, Cleaning Frequency.

(a) A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw food, or laundering wiping cloths; and drainboards or other equipment used to substitute for drainboards as specified under Chapter 7, Section 9, shall be cleaned:

(i) Before use;

(ii) Throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function; and

(iii) If used, at least every twenty four (24) hours.

Section 11. Wet Cleaning Methods.

(a) Equipment food-contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(b) The washing procedures selected shall be based on the type and purpose of the equipment or utensil, and on the type of soil to be removed.

Section 12. Warewashing Equipment, Cleaning Agents.

(a) When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified under Chapter 7, Section 7(c), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.

Section 13. Manual Warewashing Equipment, Wash Solution Temperature.

(a) The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 110^{o}F (43^{o}C) or the temperature specified on the cleaning agent manufacturer's label instructions.

Section 14. Rinsing Procedures.

(a) Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:

(i) Use of a distinct, separate water rinse after washing and before sanitizing if using:

(A) A three (3)-compartment sink;

(B) Alternative manual warewashing equipment equivalent to a three (3)-compartment sink as specified under Chapter 7, Section 7(c); or

(C) A three (3)-step washing, rinsing, and sanitizing procedure in a warewashing system for CIP equipment;

(ii) Use of a detergent-sanitizer as specified under Chapter 7, Section 20, if using:

(A) Alternative warewashing equipment as specified under Chapter 7, Section 7(c), that is approved for use with a detergent-sanitizer; or

(B) A warewashing system for CIP equipment;

(iii) Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a two (2)-compartment sink operation;

(iv) If using a warewashing machine that does not recycle the sanitizing solution as specified under Chapter 7, Section 14(a)(v), or alternative manual warewashing equipment such as sprayers, use of a nondistinct water rinse that is:

(A) Integrated in the application of the sanitizing solution; and

(B) Wasted immediately after each application; or

(v) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the sanitizing solution.

Section 15. Food-Contact Surfaces and Utensils.

(a) Equipment food-contact surfaces and utensils shall be sanitized.

Section 16. Before Use After Cleaning.

(a) Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.

Section 17. Hot Water and Chemical Sanitization.

(a) After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:

(i) Hot water manual operations by immersion for at least 30 seconds as specified under Chapter 7, Section 21;

(ii) Hot water mechanical operations by being cycled through equipment that is set up as specified under Chapter 7, Sections 21, 26 and 27, and achieving a utensil surface temperature of 160°F (71°C) as measured by an irreversible registering temperature indicator; or

(iii) Chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under Chapter 7, Section 18. Contact times shall be consistent with those on EPA-registered label use instructions by providing:

(A) Except as specified under Chapter 7, Section 17(a)(iii)(B), a contact time of at least ten (10) seconds for a chlorine solution specified under Chapter 7, Section 18(a);

(B) A contact time of at least seven (7) seconds for a chlorine solution of fifty (50) mg/l that has a pH of ten (10) or less and a temperature of at least 100°F (38°C) or a pH of eight (8) or less and a temperature of at least 75°F (24°C);

(C) A contact time of at least thirty (30) seconds for other chemical sanitizing solutions; or

(D) A contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization.

Section 18. Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

(a) A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified under Chapter 7, Section 17(a)(iii), shall meet the criteria specified in Chapter 9, Section 29 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows:

(i) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:

Concentration Range	Minimum Temperature	
mg/l	pH 10 or less °F (°C)	pH 8 or less °F (°C)
25-49	120 (49)	120 (49)
50-99	100 (38)	75 (24)
100	55 (13)	55 (13)

(ii) An iodine solution shall have a:

(A) Minimum temperature of 68 °F (20 °C);

(B) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective; and

(C) Concentration between 12.5 mg/l and 25 mg/l.

(iii) A quaternary ammonium compound solution shall:

(A) Have a minimum temperature of 75°F (24°C);

(B) Have a concentration as specified under Chapter 9, Section 29, and as indicated by the manufacturer's use directions included in the labeling; and

(C) Be used only in water with 500 mg/l hardness or less or in water having a hardness no greater than specified by the EPA-registered label use instructions.

(iv) If another solution of a chemical specified under Chapter 7, Section 18 (a) (i)-(iii) is used, the license holder shall demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution shall be approved; or

(v) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions.

Section 19. Warewashing Equipment, Clean Solutions.

(a) The wash, rinse, and sanitize solutions shall be maintained clean.

Section 20. Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

(a) If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent-sanitizer that is used in the washing step.

Section 21. Manual Warewashing Equipment, Hot Water Sanitization Temperatures.

(a) If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 171^{o}F (77^{o}C) or above.

Section 22. Manual Warewashing Equipment, Heaters and Baskets.

(a) If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:

(i) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 171^{o}F (77^{o}C); and

(ii) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

Section 23. Temperature Measuring Devices, Manual Warewashing.

(a) In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

Section 24. Sanitizing Solutions, Testing Devices and Determining Chemical Sanitizer Concentration.

(a) A test kit or other device that accurately measures the concentration in mg/l of sanitizing solutions shall be provided.

(b) Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.

Section 25. Warewashing Machine, Data Plate Operating Specifications.

(a) A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operating specifications including the:

(i) Temperatures required for washing, rinsing, and sanitizing;

(ii) Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and

(iii) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

Section 26. Warewashing Machines, Manufacturers' Operating Instructions.

(a) A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturers' instructions.

(b) A warewashing machine's conveyor speed or automatic cycle times shall be maintained and accurately timed in accordance with manufactures' specifications.

Section 27. Mechanical Warewashing Equipment, Sanitization Pressure.

(a) The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine may not be less than fifteen (15) pounds per square inch (100 kilopascals) or more than twenty five (25) pounds per square inch (170 kilopascals) as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve.

Section 28. Warewashing Machines, Flow Pressure Device.

(a) Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine; and

(b) If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a one-fourth (¼) inch or (6.4 millimeter) iron pipe size (ips) valve.

(c) Chapter 7, Section 28(a) and (b), do not apply to a machine that uses only

a pumped or recirculated sanitizing rinse.

Section 29. Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

(a) A warewashing machine that is installed after adoption of this Rule by the regulatory authority, shall be equipped to:

(i) Automatically dispense detergents and sanitizers; and

(ii) Incorporate a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizers are not delivered to the respective washing and sanitizing cycles.

Section 30. Warewashing Machines, Temperature Measuring Devices.

(a) A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:

(i) In each wash and rinse tank; and

(ii) As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.

Section 31. Warewashing Machines, Internal Baffles.

(a) Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

Section 32. Precleaning of Equipment and Utensils.

(a) Food debris on equipment and utensils shall be scraped over a waste disposal unit, or garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.

(b) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked, or scrubbed with abrasives.

Section 33. Loading of Soiled Items, Warewashing Machines.

(a) Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets, or onto conveyors, in a position that:

(i) Exposes the items to the unobstructed spray from all cycles; and

(ii) Allows the items to drain.

Section 34. Mechanical Warewashing Equipment, Wash Solution Temperature.

(a) The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:

(i) For a stationary-rack, dual-temperature machine 150ºF (66ºC);

(ii) For a stationary-rack, single-temperature machine, 165ºF (74ºC);

(iii) For a single tank, conveyor, dual temperature machine, 160ºF (71ºC);

(iv) For a multitank, conveyor, multitemperature machine 150ºF (66ºC).

(b) The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 120ºF (49ºC).

Section 35. Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(a) Except as specified under Chapter 7, Section 35(b), in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 194ºF (90ºC), or less than:

(i) For a stationary rack, single temperature machine, 165ºF (74ºC); or

(ii) For all other machines, 180ºF (82ºC).

(b) The maximum temperature specified under Chapter 7, Section 35(a), does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

Section 36. Equipment and Utensils, Air-Drying Required.

(a) After cleaning and sanitizing, equipment and utensils:

(i) Shall be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940 Sanitizing solutions, before contact with food; and

(ii) May not be cloth dried except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

Section 37. Returnables, Cleaning for Refilling.

(a) Except as specified under Chapter 7, Section 37(b) and (c), returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated establishment or processing plant.

(b) A food-specific container for beverages may be refilled at an establishment or processing plant if:

(i) Only a beverage that is not a potentially hazardous food is used as specified under Chapter 3, Section 55(a);

(ii) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home, in the establishment or processing plant;

(iii) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

(iv) The consumer-owned container returned to the establishment or processing plant for refilling is refilled for sale or service only to the same consumer; and

(v) The container is refilled by:

(A) An employee of the establishment or processing plant; or

(B) The owner of the container if the beverage system includes a contamination-free transfer process that cannot be bypassed by the container owner.

(c) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

Section 38. Equipment Reassembling.

(a) Equipment shall be reassembled so that food-contact surfaces are not contaminated.

Section 39. Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

(a) Except as specified under Chapter 7, Section 39(d), cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored:

(i) In a clean, dry location;

(ii) Where they are not exposed to splash, dust, or other contamination; and

(iii) At least six (6) inches (15 cm) above the floor.

(b) Clean equipment and utensils shall be stored as specified under Chapter 7, Section 39(a), and shall be stored:

(i) In a self-draining position that allows air drying; and

(ii) Covered or inverted.

(c) Single-service and single-use articles shall be stored as specified under Chapter 7, Section 39(a), and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(d) Items that are kept in closed packages may be stored less than six (6) inches (15 cm) above the floor on dollies, pallets, racks, and skids that are designed as provided under Chapter 6, Section 43.

Section 40. Clean Equipment Storage Prohibitions.

(a) Except as specified under Chapter 7, Section 40(b), cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored:

(i) In locker rooms;

(ii) In toilet rooms;

(iii) In garbage rooms;

(iv) In mechanical rooms;

(v) Under sewer lines that are not shielded to intercept potential drips;

(vi) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(vii) Under open stairwells; or

(viii) Under other sources of contamination.

(b) Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

Section 41. Equipment, Clothes Washers and Dryers, and Storage Cabinets; Contamination Prevention.

(a) Except as specified in Chapter 7, Section 41(b), equipment, a cabinet used for the storage of food, or a cabinet that is used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be located:

(i) In locker rooms;

(ii) In toilet rooms;

(iii) In garbage rooms;

(iv) In mechanical rooms;

(v) Under sewer lines that are not shielded to intercept potential drips;

(vi) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(vii) Under open stairwells; or

(viii) Under other sources of contamination.

(b) A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

(c) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

Section 42. Kitchenware and Tableware Handled, Displayed, Dispensed.

(a) Single-service and single-use articles and cleaned and sanitized utensils shall be handled, displayed, and dispensed so that contamination of food-contact and lip-contact surfaces is prevented.

(b) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by employees and by consumers if consumer self-service is provided.

(c) Except as specified under Chapter 7, Section 42(b), single-service articles that are intended for food-contact or lip-contact shall be furnished for consumer self-service with the original individual wrapper intact or from an approved dispenser.

Section 43. Soiled and Clean Tableware.

(a) Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.

Section 44. Preset Tableware.

(a) If tableware is preset:

(i) It shall be protected from contamination by being wrapped, covered, or inverted; or

(ii) If exposed, unused settings shall be removed when a consumer is seated; or

(iii) Exposed, unused settings shall be cleaned and sanitized before further use if the settings are not removed when a consumer is seated.

Section 45. Sanitation Requirements at Official Meat and Poultry Establishments.

(a) Each establishment must be operated and maintained in a manner

sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

(i) Sanitation requirements shall meet the requirements as specified in 9 CFR 416 Sanitation.

Section 46. Tagging Insanitary Equipment, Utensils, Rooms or Compartments.

(a) When, in the opinion of the regulatory authority, any equipment, utensil, room or compartment at an establishment is unclean or its use would be in violation of this Rule, a “Wyoming Rejected” tag may be applied.

(i) No equipment, utensil, room or compartment so tagged shall again be used until made acceptable; and

(ii) Such tag so placed shall not be removed by anyone other than the regulatory authority.

Section 47. Rinsing Equipment and Utensils after Cleaning and Sanitizing.

(a) After being cleaned and sanitized, equipment and utensils shall not be rinsed before air drying or use unless:

(i) The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified in Chapters 6 & 7; and

(ii) The rinse is applied only after the equipment and utensils have been sanitized by the application of hot water or by the application of a chemical sanitizer solution whose EPA-registered label use instructions call for rinsing off the sanitizer after it is applied in a commercial warewashing machine.

CHAPTER 8

SANITARY FACILITIES AND CONTROLS

Section 1. Approved Water Source.

(a) Drinking water shall be obtained from an approved source that is:

(i) A public water system; or

(ii) A nonpublic water system that is constructed, maintained, and operated according to law.

Section 2. Approved Water System.

(a) Water shall be received from the source through the use of:

(i) An approved public water main; or

(ii) One or more of the following that shall be constructed, maintained, and operated according to law:

(A) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances;

(B) Water transport vehicles; and

(C) Water containers.

Section 3. Alternative Water Supply.

(a) Water meeting the requirements specified under Chapter 8, Sections 1, 5 and 8, shall be made available for a mobile establishment, for a temporary establishment, an establishment or processing plant without a permanent water supply, and for an establishment or processing plant with a temporary interruption of its water supply through:

(i) A supply of containers of commercially bottled drinking water;

(ii) One or more closed portable water containers;

(iii) An enclosed vehicular water tank;

(iv) An on-premises water storage tank; or

(v) Piping, tubing, or hoses connected to an adjacent approved source.

Section 4. System Flushing and Disinfection.

(a) A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

Section 5. Quality Standards.

(a) Except as specified under Chapter 8, Section 38:

(i) Water from a public water system shall meet 40 CFR 141 National Primary Drinking Water Regulations; and

(ii) Water from a nonpublic water system shall meet the standards set by this Rule.

Section 6. Sampling.

(a) Except when used as specified under Chapter 8, Section 38, water from a nonpublic water system that will be used as drinking water in an establishment shall have a bacteriological test performed on it at least semi-annually.

Section 7. Sample Report.

(a) The most recent sample report for the nonpublic water system shall be retained on file in the establishment or processing plant.

Section 8. Capacity.

(a) The water source and system shall be of sufficient capacity to meet the peak water demands of the establishment or processing plant.

Section 9. Bottled Drinking Water.

(a) Bottled drinking water used or sold in an establishment or processing plant

shall be obtained from approved sources as specified in 21 CFR 129 Processing and Bottling of Bottled Drinking Water.

Section 10. Water Pressure.

(a) Water under pressure shall be provided to all fixtures, equipment, and non-food equipment that are required to use water except that water supplied as specified under Chapter 8, Section 3(a)(i), and (ii), to a temporary establishment or in response to a temporary interruption of a water supply need not be under pressure.

Section 11. Hot Water; 170ºF Water Required in Commercial Meat Slaughter Establishments.

(a) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the establishment or processing plant.

(b) At least 170ºF water shall be used for the sanitizing of inspection equipment and other equipment, floors, walls and the like in commercial meat slaughter establishments, which are subject to contamination by the dressing or handling of diseased carcasses, their viscera and parts.

(i) A conveniently located thermometer shall be installed to show the temperature of the water at the point of use.

Section 12. Conveying Sewage.

(a) Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.

Section 13. Removing Mobile Establishment Wastes.

(a) Sewage and other liquid wastes shall be removed from a mobile establishment at an approved waste servicing station or by a sewage transport vehicle in such a way that an imminent health hazard or nuisance is not created.

Section 14. Flushing a Waste Retention Tank.

(a) A tank for liquid waste retention shall be thoroughly flushed and drained

in a sanitary manner during the servicing operation.

Section 15. Approved Sewage Disposal System.

(a) Sewage shall be disposed through an approved facility that is:

(i) A public sewage treatment plant; or

(ii) An individual sewage disposal system that is sized, constructed, maintained, and operated according to law.

Section 16. Other Liquid Wastes and Rainwater.

(a) Condensate drainage and other non-sewage liquids and rainwater shall be drained from point of discharge to disposal in accordance with law.

Section 17. Capacity and Drainage.

(a) A sewage holding tank in a mobile establishment shall be:

(i) Sized fifteen percent (15%) larger in capacity than the water supply tank; and

(ii) Sloped to a drain that is one (1) inch (25 mm) in inner diameter or greater, and that is equipped with a shut-off valve.

Section 18. Approved System and Cleanable Fixtures.

(a) A plumbing system shall be designed, constructed, and installed according to International Plumbing Code.

(b) A plumbing fixture such as a handwashing sink, toilet, or urinal shall be easily cleanable.

Section 19. Approved Plumbing Materials.

(a) A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to the International Plumbing Code.

(b) A water filter shall be made of safe materials.

Section 20. Conditioning Device, Location.

(a) A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

Section 21. Scheduling Inspection and Service for a Water System Device.

(a) A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions; and

(b) Records demonstrating inspection and service shall be maintained by the person in charge.

Section 22. Water Reservoir of Fogging Devices, Cleaning.

(a) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(i) Maintained in accordance with manufacturer's specifications; and

(ii) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under Chapter 8, Section 22(b), whichever is more stringent.

(b) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(i) Draining and complete disassembly of the water and aerosol contact parts;

(ii) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;

(iii) Flushing the complete system with water to remove the detergent solution and particulate accumulation; and

(iv) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/l hypochlorite solution.

Section 23. Plumbing System Maintained in Good Repair.

(a) A plumbing system shall be:

(i) Repaired according to the International Plumbing Code; and

(ii) Maintained in good repair.

Section 24. Materials Approved, Water Tanks.

(a) Materials that are used in the construction of a mobile water tank, mobile establishment water tank, and appurtenances shall be:

(i) Safe;

(ii) Durable, corrosion-resistant, and nonabsorbent; and

(iii) Finished to have a smooth, easily cleanable surface.

Section 25. Enclosed System, Sloped to Drain.

(a) A mobile water tank shall be:

(i) Enclosed from the filling inlet to the discharge outlet; and

(ii) Sloped to an outlet that allows complete drainage of the tank.

Section 26. Inspection and Cleaning Port, Protected and Secured.

(a) If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank; and

(i) Flanged upward at least one-half (½) inch (13 mm); and

(ii) Equipped with a port cover assembly that is:

(A) Provided with a gasket and a device for securing the cover in place; and

(B) Flanged to overlap the opening and sloped to drain.

Section 27. "V" Type Threads, Use Limitation.

(a) A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

Section 28. Tank Vent, Protected.

(a) If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

(i) 16 mesh to 1 inch (16 mesh to 25.4 mm) screen or equivalent when the vent is in a protected area; or

(ii) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

Section 29. Inlet and Outlet, Sloped to Drain.

(a) A water tank and its inlet and outlet shall be sloped to drain.

(b) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

Section 30. Hose, Construction and Identification.

(a) A hose used for conveying drinking water from a water tank shall be:

(i) Safe;

(ii) Durable, corrosion-resistant, and nonabsorbent;

(iii) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;

(iv) Finished with a smooth interior surface; and

(v) Clearly and durably identified as to its use if not permanently attached.

Section 31. Filter, Compressed Air.

(a) A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is

used to pressurize the water tank system.

Section 32. Protective Cover or Device.

(a) A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device shall be provided for a water inlet, outlet, and hose.

Section 33. Mobile Establishment Tank Inlet.

(a) A mobile establishment's water tank inlet shall be:

(i) Three-fourths (3/4) inch (19.1 mm) in inner diameter or less; and

(ii) Provided with a hose connection of a size or type that will prevent its use for any other service.

Section 34. System Flushing and Disinfection.

(a) A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of non-use.

Section 35. Using a Pump and Hoses, Backflow Prevention.

(a) A person shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

Section 36. Protecting Inlet, Outlet, and Hose Fitting.

(a) If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under Chapter 8, Section 32.

Section 37. Tank, Pump, and Hoses; Dedication.

(a) Except as specified under Chapter 8, Section 37(b), a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.

(b) Water tanks, pumps, and hoses approved for liquid food may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

Section 38. Nondrinking Water.

(a) A nondrinking water supply shall be used only if its use is approved by the regulatory authority.

(b) Nondrinking water shall be used only for non-culinary purposes such as air-conditioning, nonfood equipment cooling, and fire protection.

Section 39. Prohibiting a Cross Connection.

(a) Except as specified in 9 CFR 308.3 (d) for firefighting, a person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.

(b) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.

Section 40. Backflow Prevention Device, Carbonator, When Required.

(a) If not provided with an air gap as specified under Chapter 8, Section 41, a dual check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 1 inch (25.4mm) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.

(b) A dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified under Chapter 8, Section 40(a).

(c) A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the establishment or processing plant, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by the regulatory authority, by:

(i) Providing an air gap as specified under Chapter 8, Section 41; or

(ii) Installing an approved backflow prevention device as specified under Chapter 8, Section 42.

Section 41. Backflow Prevention, Air Gap.

(a) An air gap between the water supply inlet and the flood level rim of the

plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than one (1) inch (25 mm).

Section 42. Backflow Prevention Device, Design Standard.

(a) A backflow or back-siphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device.

Section 43. Backflow Prevention Device, Location.

(a) A backflow prevention device shall be located so that it may be serviced and maintained.

Section 44. Grease Trap.

(a) If used, a grease trap shall be located to be easily accessible for cleaning and cleaned on a regular basis.

Section 45. Establishment Drainage System.

(a) Establishment or processing plant drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under Chapter 8, Section 18.

Section 46. Backflow Prevention, Indirect Drain.

(a) Except as specified under Chapter 8, Section 46(b), a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.

(b) A warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within five (5) feet (1.5 m) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

(c) Paragraph (a) of this Section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.

Section 47. Toilet Rooms.

(a) Toilet rooms shall be conveniently located and accessible to employees during all hours of operation.

Section 48. Toilets and Urinals.

(a) At least one (1) toilet and not fewer than the toilets required by the International Plumbing Code shall be provided. If authorized by the International Plumbing Code, and urinals are substituted for toilets, the substitution shall be done as specified in the International Plumbing Code.

Section 49. Toilet Rooms, Enclosed.

(a) A toilet room located on the premises shall be completely enclosed and provided with a tight-fitting and self-closing door except that this requirement does not apply to a toilet room that is located outside an establishment or processing plant and does not open directly into the establishment or processing plant such as a toilet room that is provided by the management of a shopping mall.

(b) Toilet room doors as specified under Chapter 8, Section 49(a), shall be kept closed except during cleaning and maintenance operations.

Section 50. Toilet Tissue, Availability.

(a) A supply of toilet tissue shall be available at each toilet.

Section 51. Toilet Room Receptacle, Covered.

(a) A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

Section 52. Handwashing Sink, Minimum Number.

(a) Except as specified under Chapter 8, Section 52(b), at least 1(one) handwashing sink, a number of handwashing sinks necessary for their convenient use by employees in areas specified under Chapter 8, Section 53, and not fewer than the number of handwashing sinks required by the International Plumbing Code shall be provided.

(b) If approved by the regulatory authority and capable of removing the types

of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands.

(c) If approved by the regulatory authority, when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

Section 53. Handwashing Sink Location.

(a) A handwashing sink shall be located:

(i) To allow convenient use by employees in food preparation, food dispensing, and warewashing areas; and

(ii) In, or immediately adjacent to, toilet rooms.

Section 54. Using a Handwashing Sink.

(a) A handwashing sink shall be maintained so that it is accessible at all times for employee use.

(b) A handwashing sink may not be used for purposes other than handwashing. Sinks used for food preparation or for washing equipment or utensils shall not be used for handwashing.

Section 55. Handwashing Sink, Water Temperature, Supply and Flow.

(a) Each handwashing sink shall be provided with hot and cold water tempered by means of a mixing valve or combination faucet.

(i) A handwashing sink shall be equipped to provide water at a temperature of at least 100°F (38°C) through a mixing valve or combination faucet.

(b) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least fifteen (15) seconds without the need to reactivate the faucet.

(c) A steam-mixing valve may not be used at a handwashing sink.

(d) An automatic handwashing facility shall be installed in accordance with manufacturer’s instructions.

Section 56. Handwashing Cleanser, Availability.

(a) Each handwashing sink or group of two (2) adjacent sinks shall be provided with a supply of hand-cleaning liquid, powder, or bar soap.

Section 57. Handwashing Aids and Devices, Use Restrictions.

(a) A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a handwashing sink as specified under Chapter 8, Section 56.

Section 58. Hand Drying Provision.

(a) Each handwashing sink or group of adjacent sinks shall be provided with:

(i) Individual, disposable towels;

(ii) A continuous towel system that supplies the user with a clean towel;

(iii) A heated-air hand drying device; or

(iv) A hand drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures.

(b) If disposable towels are used at handwashing sinks, a waste receptacle shall be located at each sink or group of adjacent sinks.

Section 59. Maintaining and Using Handwashing Sinks, Signs Posted.

(a) Handwashing sinks shall be kept clean, maintained and used as specified under Chapter 8, Section 54.

(b) A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing sinks used by food employees and shall be clearly visible to food employees.

Section 60. Waste Receptacles, Inedible Products.

(a) Except as specified under Chapter 8, Section 60(b), receptacles and waste

handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect and rodent-resistant, leakproof, and nonabsorbent.

(i) Trucks and receptacles used for inedible materials shall be of similar construction and shall bear some conspicuous and distinctive mark and shall not be used for handling edible products.

(b) Plastic bags and wet-strength paper bags may be used to line receptacles for storage inside the establishment or processing plant, or within closed outside receptacles.

Section 61. Covering Waste Receptacles.

(a) Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:

(i) Inside the establishment or processing plant if the receptacles and units:

(A) Contain food residue and are not in continuous use; or

(B) After they are filled; and

(ii) With tight-fitting lids or doors if kept outside the establishment or processing plant.

Section 62. Waste Receptacles in Vending Machines.

(a) A waste receptacle may not be located within a vending machine, except that a receptacle for beverage bottle cap closures may be located within a vending machine.

Section 63. Outside Waste Receptacles.

(a) Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the establishment or processing plant shall be designed and constructed to have tight-fitting lids, doors, or covers.

(b) Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that an accumulation of debris which attract and/or

harbor insects and/or rodents are minimized, effective cleaning is facilitated around and under the unit if it is not installed flush with the base pad.

Section 64. Waste Receptacle Drain Plugs.

(a) Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.

Section 65. Cleaning Waste Receptacles.

(a) Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified under Chapter 8, Section 12.

(b) Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

Section 66. Cleaning Implements and Supplies.

(a) Except as specified under Chapter 8, Section 66(b), suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.

(b) If approved by the regulatory authority, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

Section 67. Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units; Location.

(a) An area designated for refuse, recyclables, returnables, and, except as specified under Chapter 8, Section 67(b), a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.

(b) A redeeming machine may be located in the packaged food storage area or consumer area of an establishment or processing plant if food, equipment, utensils, linens, and single-service and single-use articles are not subject to contamination from the

machines and a public health hazard or nuisance is not created.

(c) The location of receptacles and waste handling units for refuse, recyclables, and returnables may not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.

Section 68. Storing Refuse, Recyclables, and Returnables.

(a) Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

Section 69. Areas, Enclosures, and Receptacles; Good Repair.

(a) Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables shall be maintained in good repair.

Section 70. Outside Storage Prohibitions.

(a) Except as specified under Chapter 8, Section 70(b), refuse receptacles not meeting the requirements specified under Chapter 8, Section 60, such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue may not be stored outside.

(b) Cardboard or other packaging material that does not contain food residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.

Section 71. Storage Areas, Rooms, and Receptacles.

(a) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.

(b) A receptacle shall be provided in each area of the establishment, processing plant or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.

Section 72. Maintaining Refuse Areas and Enclosures.

(a) A storage area and enclosure for refuse, recyclables, or returnables shall be kept clean and maintained free of unnecessary items, as specified under Chapter 9, Section 40.

Section 73. Indoor Storage Area.

(a) If located within the establishment or processing plant, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under Chapter 8, Sections 71 and 72, and Chapter 9, Sections 1, 2 and 9.

Section 74. Outdoor Enclosure.

(a) An outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials.

Section 75. Outdoor Storage Surface.

(a) An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable, and sloped to drain.

Section 76. Refuse Disposal Frequency.

(a) Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and/or rodents.

Section 77. Refuse Removal Receptacles or Vehicles.

(a) Refuse, recyclables, and returnables shall be removed from the premises by means of:

(i) Portable receptacles that are properly constructed and maintained; or

(ii) A transport vehicle that is properly constructed, maintained, and operated.

Section 78. Community or Individual Facility.

(a) Solid waste not disposed of through the sewage system such as through grinders and pulpers shall be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste shall be disposed of in an individual refuse facility such as a landfill or incinerator which is sized, constructed, maintained, and operated appropriately.

Section 79. Controlling Pests.

(a) The premises shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to eliminate their presence on the premises by:

(i) Routinely inspecting incoming shipments of food and supplies;

(ii) Routinely inspecting the premises for evidence of pests;

(iii) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under Chapter 8, Sections 82 and 83, and Chapter 9, Section 32; and

(iv) Eliminating harborage conditions.

Section 80. Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

(a) Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

Section 81. Insect Control Devices, Design and Installation.

(a) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(b) Insect control devices shall be installed so that:

(i) The devices are not located over a food preparation area; and

(ii) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

Section 82. Rodent Bait Stations.

(a) Rodent bait shall be contained in a covered, tamper-resistant bait station.

Section 83. Tracking Powders, Pest Control and Monitoring.

(a) A tracking powder pesticide may not be used in an establishment or processing plant.

(b) If used, a nontoxic tracking powder such as talcum or flour may not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

Section 84. Outer Openings, Protected.

(a) Except as specified under Chapter 8, Section 84(b) and (c), outer openings of an establishment or processing plant shall be protected against the entry of insects and rodents by:

(i) Filling or closing holes and other gaps along floors, walls and ceilings;

(ii) Closed, tight-fitting windows; and

(iii) Solid self-closing, tight-fitting doors.

(b) Chapter 8, Section 84(a), does not apply if an establishment or processing plant opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.

(c) Exterior doors used as exits need not be self-closing if they are:

(i) Solid and tight-fitting;

(ii) Designated by the appropriate fire protection authority for use only when an emergency exists; and

(iii) Restricted so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

(d) Except as specified under Chapter 8, Section 84(b) and (d), if the windows or doors of an establishment or processing plant, or of a larger structure within which an establishment or processing plant is located, are kept open for ventilation or other

purposes or a temporary establishment is not provided with windows and doors as specified under Chapter 8, Section 84(a), the openings shall be protected against the entry of insects and rodents by:

(i) Sixteen (16) mesh to one (1) inch (16 mesh to 25.4mm) screens;

(ii) Properly designed and installed air curtains to control flying insects; or

(iii) Other effective means.

(e) Chapter 8, Section 84(c), does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition.

(f) In processing plants that are processing honey, the doors and windows and other openings to the outside shall be properly screened and kept in good repair and equipped with bee escape or other method for disposing of the bees.

Section 85. Exterior Walls and Roofs, Protective Barrier.

(a) Perimeter walls and roofs of an establishment or processing plant shall effectively protect the establishment or processing plant from the weather and the entry of insects, rodents, and other animals.

Section 86. Operating and Storage Rooms for Inedibles; Outside Premises, Maintained in Clean Condition.

(a) All operating and storage rooms and departments of establishments used for inedible materials shall be maintained in acceptable clean conditions and meet the requirements as specified in 9 CFR 314 Handling and Disposal of Condemned or Inedible Products at Official Establishments and 9 CFR 381.95 Disposal of Condemned Poultry Products.

(b) The accumulation on the premises of establishments of any material in which flies may breed, such as hog hair, bones, paunch contents, or manure is forbidden.

CHAPTER 9

CONSTRUCTION AND MAINTENANCE OF PHYSICAL FACILITIES

Section 1. Floor, Wall, and Ceiling Surface Characteristics.

(a) Except as specified under Chapter 9, Section 1(b), materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

(i) Smooth, durable, and easily cleanable for areas where establishment or processing plant operations are conducted;

(ii) Closely woven and easily cleanable carpet for carpeted areas; and

(iii) Nonabsorbent for areas subject to moisture such as food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, mobile establishment servicing areas, and areas subject to flushing or spray cleaning methods.

(b) In a temporary establishment:

(i) If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other approved materials that are effectively treated to control dust and mud; and

(ii) Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.

Section 2. Floors, Walls, and Ceilings; Designed and Installed.

(a) Except as specified under Chapter 9, Section 3, the floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are smooth and easily cleanable, except that anti-slip floor coverings or applications may be used for safety reasons.

Section 3. Floor Carpeting, Restrictions and Installation.

(a) A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing sinks, toilets, and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(b) If carpeting is installed as a floor covering in areas other than those specified

under Section (a), it shall be:

(i) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by other approved method; and

(ii) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

Section 4. Absorbent Materials on Floors, Use Limitation.

(a) Except as specified under Chapter 9, Section 12(b), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

Section 5. Floor Covering, Mats and Duckboards.

(a) Mats and duckboards shall be designed to be removable and easily cleanable.

Section 6. Floor and Wall Junctures, Coved, and Enclosed or Sealed.

(a) In establishments or processing plants in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than one thirty-second (l/32) inch (1 mm).

(b) The floors in establishments or processing plants in which water flush cleaning methods are used shall be provided with drains and be graded to drain and the floor and wall junctures shall be coved and sealed.

Section 7. Floors, Walls, and Ceilings; Utility Lines.

(a) Utility service lines and pipes may not be unnecessarily exposed.

(b) Exposed utility service lines and pipes shall be installed to not obstruct or prevent cleaning of the floor, walls, or ceilings.

(c) Exposed horizontal utility service lines and pipes may not be installed on the floor.

Section 8. Wall and Ceiling Coverings and Coatings.

(a) Wall and ceiling covering materials shall be attached so that they are easily cleanable.

(b) Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface.

Section 9. Walls and Ceilings, Studs, Joists, and Rafters.

(a) Studs, joists, and rafters may not be exposed in areas subject to moisture. This requirement does not apply to temporary establishments.

Section 10. Walls and Ceilings, Attachments.

(a) Except as specified under Chapter 9, Section 10(b), attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall-mounted fans, decorative items, and other attachments shall be easily cleanable.

(b) In a consumer area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.

Section 11. Cleaning, Frequency and Restrictions.

(a) The physical facilities shall be cleaned as often as necessary to keep them clean.

(b) Cleaning shall be done during periods when the least amount of food is exposed, such as after closing. This requirement does not apply to cleaning that is necessary due to a spill or other accident.

Section 12. Cleaning Floors, Dustless Method.

(a) Except as specified under Chapter 9, Section 12(b), only dustless methods of cleaning shall be used, such as vacuum cleaning, wet cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.

(b) Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:

(i) Without the use of dust-arresting compounds; and

(ii) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

Section 13. Warewashing Sinks, Use Limitation.

(a) A warewashing sink may not be used for handwashing or dumping mop water.

(b) If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under Chapter 7, Section 10, before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under Chapter 7, Section 16, before and after using the sink to wash produce or thaw food.

Section 14. Cleaning Maintenance Tools, Preventing Contamination.

(a) Food preparation sinks, handwashing lavatories, and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.

Section 15. Service Sink.

(a) At least one (1) service sink or one (1) curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

(b) Toilets and urinals may not be used as a service sink for the disposal of mop water and similar liquid waste.

Section 16. Light Intensity.

(a) The light intensity shall be:

(i) At least 10 foot candles (108 lux) at a distance of thirty (30) inches (75 cm) above the floor, in walk-in refrigeration units and dry food storage areas and in other areas and rooms during periods of cleaning;

(ii) At least twenty (20) foot candles (215 lux):

(A) At a surface where food is provided for consumer self-service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption;

(B) Inside equipment such as reach-in and under-counter refrigerators;

(C) At a distance of thirty (30) inches (75 cm) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms; and

(iii) At least fifty (50) foot candles (540 lux) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders, or saws where employee safety is a factor; and

(iv) A minimum of fifty (50) foot candles (540 lux) of shadow free lighting at the inspection surfaces of the head, viscera, and carcass.

Section 17. Light Bulbs, Protective Shielding.

(a) Except as specified under Chapter 9, Section 17(b), light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed food; clean equipment, utensils, and linens; or unwrapped single-service and single-use articles.

(b) Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if:

(i) The integrity of the packages cannot be affected by broken glass falling onto them; and

(ii) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(c) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

Section 18. Mechanical Ventilation.

(a) If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

Section 19. Ventilation Hood Systems, Adequacy.

(a) Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

Section 20. Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

(a) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(b) If vented to the outside, ventilation systems may not create a public health hazard or nuisance or unlawful discharge.

Section 21. Storage of Other Personal Care Items.

(a) Except as specified under Chapter 9, Sections 37 and 38, employees shall store their personal care items in facilities as specified under Chapter 9, Section 23.

Section 22. Employee Accommodations.

(a) Areas designated for employees to eat, drink, and use tobacco shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

(b) Lockers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles cannot occur.

Section 23. Dressing Rooms and Lockers.

(a) Dressing rooms shall be designated and used by employees if the employees regularly change their clothes in the establishment or processing plant.

(b) Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.

(c) In new construction, lockers or other suitable facilities shall be provided for the orderly storage of employees' clothing and other possessions.

Section 24. Presence and Use of Toxic Materials.

(a) Only those poisonous or toxic materials that are required for the operation and maintenance of an establishment or processing plant, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in an establishment or processing plant.

(b) Chapter 9, Section 24(a) does not apply to packaged poisonous or toxic materials that are for retail sale.

Section 25. Identifying Information, Prominence.

(a) Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label.

Section 26. Working Containers, Chemicals.

(a) Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material.

Section 27. Chemical Storage.

(a) Poisonous or toxic materials shall be stored so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

(i) Separating the poisonous or toxic materials by spacing or partitioning; and

(ii) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This paragraph does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

Section 28. Storage and Display.

(a) Poisonous or toxic materials shall be stored and displayed for retail sale so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

(i) Separating the poisonous or toxic materials by spacing or partitioning; and

(ii) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

Section 29. Sanitizers, Criteria.

(a) Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).

Section 30. Drying Agents, Criteria.

(a) Drying agents used in conjunction with sanitization shall:

(i) Contain only components that are listed as one of the following:

(A) Generally recognized as safe for use in food as specified in 21 CFR 182 -Substances Generally Recognized as Safe, or 21 CFR 184 -Direct Food Substances Affirmed as Generally Recognized as Safe;

(B) Generally recognized as safe for the intended use as specified in 21 CFR 186 -Indirect Food Substances Affirmed as Generally Recognized as Safe;

(C) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 -Prior-Sanctioned Food Ingredients;

(D) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR parts 175 Indirect Food Additives: Adhesives and Components of Coatings through 21 CFR 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; or

(E) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; and

(ii) When sanitization is with chemicals, the approval required under Chapter 9, Section 30(a)(i)(C) or (a)(i)(E), or as an indirect food additive required under Chapter 9, Section 30(a)(i)(D), shall be specifically for use with chemical sanitizing solutions.

Section 31. Lubricants.

(a) Lubricants shall meet the requirements specified in 21 CFR 178.3570 Lubricants with incidental food contact, if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.

Section 32. Restricted Use Pesticides, Criteria.

(a) Restricted use pesticides specified under Chapter 9, Section 34(a)(iii), shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.

Section 33. Boiler Water Additives, Criteria.

(a) Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 Boiler Water Additives.

Section 34. Conditions of Use.

(a) Poisonous or Toxic Materials shall be:

(i) Used according to:

(A) Law and this Rule;

(B) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in an establishment;

(C) The conditions of certification, if certification is required, for use of the pest control materials; and

(D) Additional conditions that may be established by the regulatory authority; and

(ii) Applied so that:

(A) A hazard to employees or other persons is not constituted; and

(B) Contamination including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted-use pesticide, this is achieved by:

(I) Removing the items;

(II) Covering the items with impermeable covers; or

(III) Taking other appropriate preventive actions; and

(IV) Cleaning and sanitizing equipment and utensils after the application.

(iii) A restricted use pesticide shall be applied only by an applicator certified as defined in 7 U.S.C. 136(e) certified applicator, of the federal insecticide, fungicide and rodenticide act, or a person under the direct supervision of a certified applicator.

Section 35. Poisonous or Toxic Material Containers.

(a) A container previously used to store poisonous or toxic materials may not be used to store, transport, or dispense food.

Section 36. Medicines.

(a) Only those medicines that are necessary for the health of employees shall be allowed in an establishment or processing plant. This Section does not apply to medicines that are stored or displayed for retail sale.

(b) Medicines that are in an establishment or processing plant for the employees' use shall be labeled as specified under Chapter 9, Section 25, and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

Section 37. Refrigerated Medicines, Storage.

(a) Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

(i) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; and

(ii) Located so they are inaccessible to children.

Section 38. First Aid Supplies.

(a) First aid supplies that are in an establishment or processing plant for the employees' use shall be:

(i) Labeled as specified under Chapter 9, Section 25; and

(ii) Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

Section 39. Facilities in Good Repair.

(a) The physical facilities shall be maintained in good repair.

Section 40. Maintaining Premises, Unnecessary Items and Litter.

(a) The premises shall be free of:

(i) Items that are unnecessary to the operation or maintenance of the establishment or processing plant such as equipment that is nonfunctional or no longer used; and

(ii) Litter.

Section 41. Private Homes and Living or Sleeping Quarters, Use Prohibition.

(a) A private home, a room used as living or sleeping quarters or an area directly opening into a room used as living or sleeping quarters may not be used for conducting an establishment or processing plant operations.

Section 42. Living or Sleeping Quarters, Separation.

(a) Living or sleeping quarters located on the premises of an establishment or processing plant such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for an establishment or processing plant operations by complete partitioning and solid self-closing doors.

Section 43. Clothes Washers and Dryers.

(a) Except as specified in Chapter 9, Section 43(b), if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer shall be provided and used.

(b) If on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under Chapter 9, Section 46, a mechanical clothes washer and dryer need not be provided.

Section 44. Use of Laundry Facilities.

(a) Except as specified under Chapter 9, Section 44(b), laundry facilities on the premises of an establishment shall be used only for the washing and drying of items used in the operation of the establishment or processing plant.

(b) Separate laundry facilities located on the premises for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering establishment or processing plant items.

Section 45. Mechanical Washing.

(a) Except as specified under Chapter 9, Section 45(b), linens shall be mechanically washed.

(b) In establishments or processing plants in which only wiping cloths are laundered as specified under Chapter 9, Section 43(b), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a warewashing or food preparation sink that is cleaned as specified under Chapter 7, Section 10.

Section 46. Wiping Cloths, Air-Drying Locations.

(a) Wiping cloths laundered in an establishment or processing plant that does not have a mechanical clothes dryer as specified under Chapter 9, Section 43(b), shall be air-dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens, single-service and single-use articles and the wiping cloths. This Section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under Chapter 7, Section 18.

Section 47. Clean Linens.

(a) Clean linens shall be free from food residues and other soiling matter.

Section 48. Linen Specifications.

(a) Linens that do not come in direct contact with food shall be laundered

between operations if they become wet, sticky, or visibly soiled.

(b) Cloth gloves used as specified under Chapter 5, Section 7(d), shall be laundered before being used with a different type of raw animal food such as beef, lamb, pork, and fish.

(c) Linens and napkins that are used as specified under Chapter 3, Section 24, and cloth napkins shall be laundered between each use.

(d) Wet wiping cloths shall be laundered daily.

(e) Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

Section 49. Storage of Soiled Linens.

(a) Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles.

Section 50. Drying Mops.

(a) After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.

Section 51. Storing Maintenance Tools.

(a) Maintenance tools such as brooms, mops, vacuum cleaners and similar items shall be:

(i) Stored so they do not contaminate food, utensils, equipment, linens, and single-service and single-use articles; and

(ii) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

Section 52. Prohibiting Animals.

(a) Except as specified under Chapter 9, Section 52(b) and (c), live animals may not be allowed on the premises of an establishment or processing plant.

(b) Live animals may be allowed in the following situations if the

contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result:

(i) Edible fish, or decorative fish in aquariums, shellfish, or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

(ii) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

(iii) In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person if a health or safety hazard will not result from the presence or activities of the service animal; and

(iv) Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

(A) Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas;

(B) Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present; and

(C) Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and

(v) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly restricted, such as in a variety store that sells pets or a tourist park that displays animals.

(c) Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result.

Section 53. Outdoor Surface Characteristics.

(a) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(b) Exterior surfaces of buildings and mobile establishments or processing plants shall be of weather-resistant materials.

(c) Outdoor storage areas for refuse, recyclables, or returnables shall be of

materials specified under Chapter 8, Sections 74 and 75.

Section 54. Outdoor Food Vending Areas, Overhead Protection.

(a) If located outside, a machine used to vend food shall be provided with overhead protection except that machines vending canned beverages need not meet this requirement.

Section 55. Outdoor Servicing Areas, Overhead Protection.

(a) Servicing areas shall be provided with overhead protection except that areas used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, need not be provided with overhead protection.

Section 56. Outdoor Walking and Driving Surfaces, Graded to Drain.

(a) Exterior walking and driving surfaces shall be graded to drain.

Section 57. Outdoor Refuse Areas, Curbed and Graded to Drain.

(a) Outdoor refuse areas shall be curbed and graded to drain to collect and dispose of liquid waste resulting from the refuse and/or from cleaning the area and waste receptacles.

Section 58. Facilities, Sanitation at Official Establishments Requiring Inspection.

(a) Official establishments shall be adequate for conducting inspection and meet the requirements specified in 9 CFR 307 Facilities For Inspection; 416 Sanitation; and 9 CFR 381 Poultry Products Inspection Regulations, Subpart G Facilities for Inspection; Overtime and Holiday Service; Billing Establishments, Subpart H Sanitation, and Subpart I Operating Procedures.

CHAPTER 10

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

Section 1. When a HACCP Plan is Required.

(a) Before engaging in an activity that requires a HACCP plan, a license applicant or license holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under Chapter 10, Section 2, and the relevant provisions of this Rule if:

(i) Submission of a HACCP plan is required according to law;

(ii) A variance is required as specified under Chapter 3, Sections 41(d)(iv), 62, or Chapter 6, Section 18 (b); or

(iii) The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under Chapter 2, Section 7, an inspection finding, or a variance request.

(b) A license applicant or license holder shall have a properly prepared HACCP plan as specified under Chapter 3, Section 63.

Section 2. Contents of a HACCP Plan.

(a) For an establishment or processing plant that is required under Chapter 10, Section 1, to have a HACCP plan, the plan and specification shall indicate:

(i) A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or other foods that are specified by the regulatory authority;

(ii) A flow diagram by specific food or category type identifying critical control points and providing information on the following:

(A) Ingredients, materials, and equipment used in the preparation of that food; and

(B) Formulations, or recipes that delineate methods and procedural control measures that address the food safety concerns involved;

(iii) Food employee and supervisory training plan that addresses the food safety issues of concern;

(iv) A statement of standard operating procedures for the plan under consideration including clearly identifying:

(A) Each critical control point;

(B) The critical limits for critical control point;

(C) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge;

(D) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;

(E) Action to be taken by the person in charge if the critical limits for each critical control point are not met;

(F) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed; and

(v) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

Section 3. Trade Secrets.

(a) The regulatory authority shall treat as confidential in accordance with law information that meets criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under Chapter 2, Section 7, and Chapter 10, Section 2.

Section 4. HACCP Plans Required in Official Meat and Poultry Establishments.

(a) Every official establishment shall have a written HACCP plan as specified in 9 CFR 417 Hazard Analysis and Critical Control Point (HACCP) Systems.

CHAPTER 11

BOTTLED WATER REQUIREMENTS

Section 1. Water Quality and Source.

(a) All bottled water except mineral water shall meet quality standards prescribed in 21 CFR 165.110 Bottled Water. Mineral water shall not contain any contaminant in quantities injurious to health taking into account the natural constituents and the rate of consumption of mineral water, as compared to drinking water.

Section 2. Good Manufacturing Practices and Operational Requirements.

(a) All bottled water, including mineral water, shall be processed and packaged in accordance with 21 CFR 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, and 21 CFR 129 Processing and Bottling of Bottled Drinking Water.

(b) Bottled water shall not be processed or bottled through a line or other equipment that is used for any other food.

(c) Artesian water may be collected with the assistance of external force to enhance the natural underground pressure so long as such measures do not alter the composition and quality of the water.

(d) Natural water may be treated to reduce the concentration of any substance which exceeds standards set under 21 CFR. 165.110 Bottled Water. It may be collected and transported by pipes, tunnels, trucks and similar devices.

(e) Spring water shall be collected only at the natural orifice of the spring or through a bore hole that is adjacent to the natural orifice. Spring water collected with the assistance of external force to protect the water source shall retain all the physical properties of and be of the same composition and quality as the water that flows naturally to the surface of the earth.

Section 3. Source Water Sampling.

(a) Water samples shall be:

(i) Taken from approved sources by the plant as often as necessary but at least annually to assure compliance with 21 CFR 129.35 (a) (3) Sanitary Facilities;

(ii) Analysis for microbiological contaminants shall be weekly if the source is other than a public water system;

(iii) The sampling and analyses shall be by qualified personnel and shall be in addition to any sampling performed by government agencies or laboratory;

(iv) Records of the sampling and analyses shall be maintained on file at the plant for two years;

(v) Analysis of the samples shall be performed by an accredited Laboratory;

(vi) Analysis for chemical contaminants shall be at a minimum frequency of once each year; and

(vii) Analysis for radiological contaminants shall be at a minimum frequency of once every four (4) years.

Section 4. Finished Product Sampling.

(a) To assure the plant's production of bottled water is in compliance with 21 CFR 129.80 Processes and Controls, the following product analyses shall be performed by an accredited laboratory:

(i) According to 21 CFR 129.80 Processes and Controls, analyze a representative sample from a batch or segment of a continuous production for each type of bottled water produced by the plant at least weekly for microbiological purposes; and

(ii) According to 21 CFR 129.80 Processes and Controls, analyze a representative sample from a batch or segment of continuous product run for each type of bottled drinking water produced by the plant at least annually for chemical, physical, and radiological purposes.

(b) The representative sample shall be derived from the bottled product.

(c) All records pertaining to sampling and analysis shall be maintained at the plant for two years. All required documents shall be available for official review upon request.

Section 5. Exemptions.

(a) A bottled water plant operator may request an exemption from sampling source water and finished product if bottling is conducted less than on a weekly basis.

(i) An operator exempted under this section shall sample source water and finished products each production day.

(b) Bottled soda or seltzer or other food complying with 21 CFR 165.110 Bottled Water, is exempt from the requirements of this Rule.

CHAPTER 12

BULK WATER REQUIREMENTS

Section 1. Applicability.

(a) This Rule applies to all persons engaged in the business of hauling bulk quantities of water for human consumption or for use in a licensed establishment or processing plant.

(i) Bulk water haulers shall be licensed according to Chapter 2, Section 2.

Section 2. General Standards.

(a) All bulk water covered shall be obtained from an approved source meeting one (1) of the following requirements:

(i) A regulated public water system that meets the requirements of 40 CFR 141 which is designed, operated, maintained, and sampled according to law;

(ii) A non-public water system that is designed, operated, and maintained according to law with current satisfactory or negative sampling results for coliform bacteria where samples are collected at least semiannually; or

(iii) An approved well or developed spring with an established history of current satisfactory or negative sampling results for coliform bacteria; and

(A) Routine sampling conducted at least quarterly or immediately prior to filling the bulk tank.

(b) Bulk water to be hauled, sold, or used shall not contact any surface or object which is not specifically designed for the sanitary handling and transfer of potable water. All equipment and plumbing coming in contact with the bulk water must be used exclusively for handling potable water and not for any other purpose.

(c) Tanks previously used to haul any beverage, food, or food-grade substance other than potable water, shall be tested for volatile organic chemicals (VOC) and inorganic chemicals (IOC) before being put into service.

(d) Tanks which have previously been used for hauling non-food grade liquids or petroleum products shall not be used to haul potable water.

(e) Bulk water tanks shall be completely sealed and latched at all times except when filling, cleaning, or servicing the bulk tank.

(i) Air vents shall terminate downward, if not otherwise protected by the manhole cover, and be equipped with a dust filter capable of removing particulate material which exceeds 10 microns in diameter.

(A) A twenty four (24) mesh, or finer, screen may be used during the winter months if the filter is likely to become frozen.

(f) All licensed bulk water hauling tanks shall display a “Wyoming Tested and Approved” seal on the outside of the tank or inside the water handling equipment compartment showing the most recent date of inspection.

(g) Water shall not be stored in the bulk tank longer than three (3) days.

Section 3. Vehicle Identification.

(a) The name and address of the person or firm hauling bulk water shall:

(i) Appear on both sides of the tank, or

(ii) On both of the truck cab doors if the bulk tank is not a separate unit.

(A) The size of the lettering shall be at least four (4) inches (10 cm) in height; and

(B) Must be fully visible and legible at all times.

(b) The words “drinking water only” or "potable water only" shall:

(i) Appear on both sides of the tank in letters at least four (4) inches (10 cm) in height;

(ii) On the rear of the tank in letters at least two (2) inches (5 cm) in height; and

(iii) Must be fully visible and legible at all times.

Section 4. Vehicle and Equipment Standards.

(a) All containers, tanks, hoses, fittings, caps and other equipment used to haul, store or transfer bulk water shall:

(i) Be constructed of approved food grade materials and coatings as defined in 40 CFR 141 and 21 CFR 174 and 175.

(b) All pumps must be constructed of food grade, corrosion resistant materials, and have permanently sealed, self-lubricating bearings.

(c) All parts of the tank, filling system, delivery system and associated pumps and hoses must be readily accessible for cleaning and inspection.

(d) All hoses and tubing shall:

(i) Be provided with threaded or clamped caps; and

(ii) The caps shall be in place at all times the fitting or hose is not in use.

(A) All caps shall be appropriately tethered to equipment to prevent loss and misuse.

(e) When hose bibs are available for filling canteens or portable water containers, a vacuum breaker shall be used to prevent backflow contamination.

(i) All hose bibs shall be provided with caps and shall be kept capped except when in use.

(f) All bulk tank openings and valves shall be kept closed and completely sealed at all times to prevent contamination from entering the tank.

(g) A manhole shall be provided for routine maintenance, cleaning and sanitizing.

(i) The manhole shall be large enough to enter for inspection.

(h) A drain at the lowest point in the tank shall be provided to allow for complete drainage.

(i) All reducers, adapters, pipe fittings and any other water-handling equipment carried on board must be stored protected in dust-proof containers.

(j) All tank valves and other openings shall be kept closed, latched, and sealed when not in use.

Section 5. Fill Point Standards.

(a) When using an overhead standpipe filling source, the filler hose shall terminate at least two hose diameters above the overflow of the tank and must be supported by a device which will provide for overhead protection of the fill hole.

(i) Threaded or clamped caps must be attached to the discharge and entry points of the standpipe and shall be used to protect the standpipe when it is not in use for filling.

(b) When filling through a direct connection:

(i) A vacuum breaker or other suitable means to prevent backflow from the bulk tank into the water system is required at the filling source; and

(ii) Filler hoses remaining attached to a hydrant shall be:

(A) Tightly capped; and

(B) Stored off the ground; or

(C) Flushed; and

(D) The connecting end sprayed with a sanitizing solution prior to connecting to the bulk tank.

Section 6. Discharge Requirements.

(a) When water is discharged from the bulk tank, the manhole and all other openings to the air must remain closed and be properly vented and screened to prevent the entrance of contaminants.

(b) The fill hose opening of the receiving tank must be protected from contamination during the filling procedure.

(c) During discharge, backflow of water from the receiving tank to the discharge (bulk) tank shall be prevented by one of the following methods:

(i) Maintaining an air gap between the discharge hose and the receiving tank;

(ii) Use of a vacuum breaker on the bulk tank or it’s pump; or

(iii) By elevating and securing the discharge hose six (6) inches above

the filler neck or overflow pipe of the discharge (bulk) tank.

Section 7. Sampling and Evaluation.

(a) A water sample from the tanker shall be submitted to an accredited laboratory by the hauler for a Coliform determination at least every six (6) months and after an extended interruption of water hauling services on the tanker.

(i) The sample shall be collected from the most commonly used discharge port of the bulk tank; and

(ii) A copy of the results shall be provided to the regulatory authority upon request.

Section 8. Records.

(a) The water hauler shall maintain a log of activities including:

(i) Dates, times, and quantities of all bulk water deliveries;

(ii) All water source(s);

(iii) All delivery points including addresses;

(iv) Copies of all agreements and contracts;

(v) Results of all required bacteriological analysis of samples collected from the bulk tank; and

(vi) A record of all cleaning, maintenance, and bulk tank repairs.

(b) These records shall be maintained for two (2) years in a central location and made available for review by the regulatory authority.

Section 9. Exemptions.

(a) Persons hauling water for their own use or for the use of their non-paying guests are not subject to the requirements of this Rule, providing they are not engaged in a profit oriented enterprise or sponsor of a free business or recreational camp where the public would be expected to consume the water.

(b) In emergency situations, equipment and/or water not approved under the auspices of this Rule shall be approved by the regulatory authority if all of the following conditions are met:

(i) The equipment selected for emergency use shall not have been previously used for hauling substances that are potentially unsafe for humans, such as sewage or chemicals;

(ii) All equipment must be thoroughly cleaned and sanitized before use;

(iii) The water shall be sufficiently disinfected to insure it is safe for human consumption; and

(iv) An exemption shall only be granted after inspection and approval by the regulatory authority.

Section 10. Sanitation.

(a) All water transfer equipment and any other equipment having the possibility of coming in contact with the bulk water shall be washed, rinsed, sanitized, and replaced as often as necessary to effectively maintain the sanitary quality of the bulk water.

(b) The bulk tank interior must be visually inspected by the hauler prior to the initial filling each day, and whenever potential contamination is suspected.

(c) The inside of the bulk tank must be cleaned and sanitized:

(i) Any time contamination has occurred or possibly occurred;

(ii) After back siphonage of water has occurred from a receiving tank;

(iii) When a visual inspection reveals sediment, rust, or foreign material inside the tank;

(iv) After more than thirty (30) days of non-use;

(v) After repairs have been made to the inside of the tank;

(vi) After filling with water from a source where a “boil order” has been imposed; and

(vii) Upon receipt of unsatisfactory results from a routine bacteriological test of water drawn from the tank.

(d) Approved methods for sanitizing bulk tanks include:

(i) Manual (by brushing, spraying, or immersion) application of a sanitizing solution containing chlorine (200 ppm) or quartenary ammonium (200-400 ppm) directly to all interior tank surfaces, allowing a 30 minute contact time then followed by a potable water rinse;

(ii) Filling the tank with a diluted (50 ppm) chlorine sanitizing solution and allowing it to sit in the tank for twenty four (24) hours. Approximately one (1) gallon of bleach containing 5.25% sodium hypochlorite will make one thousand (1,000) gallons of a sanitizing solution with a concentration of fifty (50) ppm. A chemical test kit must be used for verifying the concentration of sanitizers; or

(iii) Steam contact application to the interior surfaces of the bulk tank.

(e) A spray bottle or tank sprayer containing either a chlorine (100-200 ppm) or quaternary ammonium (200-400 ppm) sanitizing solution shall be kept with the hauler at all times.

(i) Sanitizing solutions shall be applied as needed to pipe fittings, hose bibs, caps, tank openings and other possible points of contamination.

(f) Good hygiene shall be practiced by the hauler during filling, delivery and handling equipment including:

(i) Avoid touching the interior surfaces of hoses, clamps, fittings, and covers;

(ii) Prevent the contamination or unnecessary handling of any surface inside a receiving tank; and

(iii) Hand washing, use of disposable gloves, or the application of an alcohol-based gel-type hand sanitizer is required before handling any equipment surface that may come in contact with the bulk water.

CHAPTER 13

FOOD SALVAGE

Section 1. Handling of Distressed Merchandise.

(a) Any person owning or having possession of distressed merchandise shall contact the director:

(i) Within 24 hours after the merchandise becomes distressed; and

(ii) Prior to its removal from the place at which it was located when it became distressed merchandise.

(b) If emergency removal of such distressed merchandise is required, or immediate contact with the director cannot be made, such notice to the director shall be made as soon thereafter as possible.

(c) The salvage distributor or manager of the salvage processing plant shall contact the director within forty-eight (48) hours whenever distressed merchandise subject to the provisions of this Rule is obtained.

(d) Distressed and salvageable merchandise shall:

(i) Be moved from the site of a fire, flood, sewer backup, wreck or other cause as expeditiously as possible so as not to become putrid, a rodent or insect harborage, or otherwise a menace to public health;

(ii) If of a perishable nature prior to reconditioning, be transported only in vehicles provided with adequate refrigeration if necessary for product maintenance; and

(iii) Not be shipped interstate without prior approval of the director.

(e) Distressed articles other than food that are also salvaged shall be handled in rooms separate from those in which foods are reconditioned.

(f) Sufficient precautions shall be taken to prevent cross-contamination (animal feed to human food, etc.) among the various types of merchandise which are salvageable or salvaged.

(g) Contaminated foods shall be separated immediately from non-contaminated foods.

Section 2. Reconditioning and Labeling of Distressed Merchandise.

(a) All salvageable merchandise shall be reconditioned prior to sale or distribution except for such sale or distribution to a person who meets all applicable requirements of this Rule and is acceptable to the director.

(b) All metal cans of food offered for sale or distribution shall be essentially free from rust (pitting) and dents (especially at rim, end double seams and/or side seams).

(i) Leakers, springers, flippers, and swells shall be deemed unfit for sale or distribution.

(ii) Metal or glass containers of food with press caps, screw caps, pull rings or other types of openings which have been in contact with:

(A) Water, liquid foam; or

(B) Other deleterious substances, as a result of fire fighting efforts, flood, sewer backups or similar mishaps, shall be:

(I) Deemed unfit for sale or distribution, and considered non-salvageable merchandise.

(c) Metal containers of food, other than those mentioned in (b) above:

(i) Whose integrity has not been compromised;

(ii) Whose integrity would not be compromised by reconditioning; and

(iii) Which have been partially or totally submerged in water, liquid foam, or other deleterious substance as the result of flood, sewer backup or other reasons shall be:

(A) Thoroughly cleaned; and

(B) Subjected to a sanitizing rinse of a concentration of 100 ppm available chlorine for a minimum period of one minute; or

(C) Sanitized by another method approved by the director.

(iv) Shall subsequently be treated to inhibit rust formation.

(d) Cans or tins showing surface rust shall have:

(i) Labels removed;

(ii) The outer surface cleaned by buffing;

(iii) A protective coating applied when necessary; and

(iv) New labels applied.

(e) Relabeling of other salvageable non-metal (glass, plastic, etc.) containers shall be required when original labels are missing or illegible.

(f) All salvageable merchandise shall:

(i) Be labeled to indicate that the merchandise has been salvaged; and

(ii) Be in containers provided with labels meeting the requirements of W.S. 35-7-119 Fair packaging and labeling provisions, and regulations promulgated under that Act for products in interstate commerce.

(d) If original labels that are removed from containers which are to be resold or redistributed, the distributor must show the name and address of the salvage processing plant, as well as the date of reconditioning for sale or distribution.

Section 3. Handling of Non-Salvageable Merchandise.

(a) Foods shall be deemed to be non-salvageable merchandise if:

(i) They are contaminated and/or adulterated by pesticides or other chemicals;

(ii) They are potentially hazardous foods which have been exposed to a temperature above 41EF (5EC) for a period exceeding four (4) hours;

(iii) They are foods found unfit for salvage upon examination;

(iv) They are foods packaged in paper or other porous materials which have been subject to contamination; and

(v) They are foods so packaged that contaminating residues cannot be removed.

(b) Non-salvageable merchandise shall not be sold or distributed as food, but shall be disposed of in a manner approved by and under the supervision of the regulatory authority.

Section 4. Records.

(a) A written record or receipt of distressed, salvageable and salvaged merchandise shall be kept by the salvage processing plant for inspection by the regulatory authority during business hours.

(i) The records shall include:

(A) The name of the product;

(B) The name and address of the manufacturer or distributor;

(C) The production code;

(D) Container sizes;

(E) Source of the distressed merchandise;

(F) The date received;

(G) The type of damage; and

(H) The salvage process conducted.

(ii) These records shall be kept on the premises of the salvage processing plant for a period of two (2) years following the completion of transactions.

(b) A written record shall be kept by salvage handlers on forms provided by the director.

(i) The record shall include, among other information requested by the director:

(A) Name and address of manufacturer or distributor;

(B) Description of food;

(C) Production codes;

(D) Container sizes;

(E) Date and time of accident or other event which caused merchandise to be distressed;

(F) Date and time of removal;

(G) Hours without refrigeration, when applicable;

(H) Type and extent of damage;

(I) Methods used for moving;

(J) Amount of merchandise destroyed;

(K) Method of destruction;

(L) Landfill receipt number;

(M) Location of landfill; and

(N) License and trailer numbers of all vehicles used to transport distressed food.

Section 5. Embargo of Distressed Food.

(a) Whenever a "notice of embargo" has been placed on or about any premises or vehicle by the regulatory authority, any person, acting as a salvage handler, must handle the distressed merchandise within the conditions outlined on the notice.

(i) The Anotice of embargo@ must be kept in the general area of the distressed merchandise at all times.

(b) Distressed merchandise which is under embargo may be transferred and moved to a nearby location for further handling.

(i) In all cases the regulatory authority must be notified when distressed merchandise is moved.

(c) Upon final disposition of all distressed merchandise, the salvage handler must return the "notice of embargo" and all other records required by this Rule to the regulatory authority within three (3) days.

CHAPTER 14

FEDERAL REGULATIONS

Section 1. Adoption of Federal Regulations.

(a) For the purpose of all Chapters, the citations herein are referenced throughout this Rule.

(i) The Code of Federal Regulations (CFR): 7 CFR 56 Regulations Governing the Voluntary Grading of Shell Eggs; 7 CFR 57 Inspection of Eggs (Egg Products Inspection Act); 7 CFR 60 Country of Origin Labeling for Fish and Shellfish; 7 CFR 65 Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Macadamia Nuts, and Peanuts; 9 CFR 301 Definitions; 9 CFR 302 Application of Inspection and Other Requirements; 9 CFR 303 Exemptions; 9 CFR 304 Application for Inspection; Grant of Inspection; 9 CFR 305 Official Numbers; Inauguration of Inspection; Withdrawal of Inspection; Reports of Violation; 9 CFR 306 Assignment and Authorities of Program Employees; 9 CFR 307 Facilities for Inspection; 9 CFR 309 Antemortem Inspection; 9 CFR 310 Postmortem Inspection; 9 CFR 311 Disposal of Diseased or Otherwise Adulterated Carcasses and Parts; 9 CFR 312 Official Marks, Devices and Certificates; 9 CFR 313 Humane Slaughter of Livestock; 9 CFR 314 Handling and Disposal of Condemned or other Inedible Products at Official Establishments; 9 CFR 315 Rendering or other Disposal of Carcasses and Parts Passed for Cooking; 9 CFR 316 Marking Products and Their Containers; 9 CFR 317 Labeling, Marking Devices, and Containers; 9 CFR 318 Entry into Official Establishments; Reinspection and Preparation of Products; 9 CFR 319 Definitions and Standards of Identity or Composition; 9 CFR 320 Records, Registration, and Reports; 9 CFR 321 Cooperation with States and Territories; 9 CFR 325 Transportation; 9 CFR 329 Detention; Seizure and Condemnation; Criminal Offenses; 9 CFR 352 Exotic Animals; Voluntary Inspection; 9 CFR 354 Voluntary Inspection of Rabbits and Edible Products Thereof; 9 CFR 362 Voluntary Poultry Inspection Regulations; 9 CFR 381 Poultry Products Inspection Regulations; 9 CFR 412 Label Approval; 9 CFR 416 Sanitation; 9 CFR 417 Hazard Analysis and Critical Control Point (HACCP) Systems; 9 CFR 418 Recalls; 9 CFR 424 Preparation and Processing Operations; 9 CFR 430 Requirements for Specific Classes of Product (*Listeria monocytogenes*); 9 CFR 441.10 Retained Water; 9 CFR 442 Quantity of Contents Labeling and Procedures and Requirements for Accurate Weights; 9 CFR 500 Rules of Practice; 9 CFR 590 Inspection of Eggs and Egg Products (Egg Products Inspection Act); 21 CFR 1.20-1.24 Subpart B-General Labeling Requirements; 21 CFR 7.1-7.13 Enforcement Policy Subpart A-General Provisions and 7.40-7.59 Subpart C-Recalls (Including Product Corrections)-Guidance on Policy, Procedures, and Industry Responsibilities; 21 CFR 70 Color Additives; 21 CFR 73.1-73.615 Listing of Color Additives Exempt From Certification Subpart A-Foods; 21 CFR 74.101-74.706 Listing of Color Additives Subject to Certification Subpart A-Foods; 21 CFR 81 General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics; 21 CFR 82.3-82.706 Listing of Certified Provisionally Listed Colors and Specifications Subpart A-General Provisions and Subpart B-Drugs and Cosmetics; 21 CFR 100.155 Salt and Iodized Salt; 21 CFR 101 Food Labeling; 21 CFR 102 Common or Usual Name for Nonstandardized Foods (except 102.19); 21

CFR 104 Nutritional Quality Guidelines for Foods; 21CFR 105 Foods for Special Dietary Use; 21 CFR 108.25-108.35 Emergency Permit Control Subpart B-Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit; 21CFR 109 Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material; 21 CFR 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food; 21 CFR 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; 21 CFR 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; 21 CFR 114 Acidified foods; 21 CFR 115 Eggs, Refrigeration; 21 CFR 120 Hazard Analysis and Critical Control Point (HACCP) Systems; 21 CFR 123 Fish and Fishery Products; 21 CFR 129 Processing and Bottling of Bottled Drinking Water; 21 CFR 130 Food Standards: General; 21 CFR 131 Milk and Cream; 21 CFR 133 Cheeses and Related Cheese Products; 21 CFR 135 Frozen Desserts; 21 CFR 136 Bakery Products; 21 CFR 137 Cereal Flours and Related Products; 21 CFR 139 Macaroni and Noodle Products; 21 CFR 145 Canned Fruits; 21 CFR 146 Canned Fruit Juices; 21CFR 150 Fruit Butters, Jellies, Preserves, and Related Products; 21 CFR 152 Fruit Pies; 21 CFR 155 Canned Vegetables; 21 CFR 156 Vegetable Juices; 21 CFR 158 Frozen Vegetables; 21 CFR 160 Eggs and Egg Products; 21 CFR 161 Fish and Shellfish; 21 CFR 163 Cacao Products; 21 CFR 164 Tree Nut and Peanut Products; 21 CFR 165 Beverages; 21CFR 166 Margarine; 21 CFR 168 Sweeteners and Table Syrups; 21 CFR 169 Food Dressings and Flavorings; 21 CFR 170 Food Additives; 21 CFR 171 Food Additive Petitions; 21 CFR 172 Food Additives Permitted for Direct Addition to Food for Human Consumption; 21 CFR 173 Secondary Direct Food Additives Permitted in food for Human Consumption; 21 CFR 174 Indirect Food Additives: General; 21 CFR 175 Indirect Food Additives: Adhesives and Components of Coatings; 21 CFR 176 Indirect Food Additives: Paper and Paperboard Components; 21 CFR 177 Indirect Food Additives: Polymers; 21 CFR 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; 21 CFR 179 Irradiation in the Production, Processing and Handling of Food; 21 CFR 180 Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study; 21 CFR 181 Prior-Sanctioned Food Ingredients; 21 CFR 182 Substances Generally Recognized as Safe; 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe; 21 CFR 186 Indirect Substances Affirmed as Generally Recognized as Safe; 21 CFR 189 Substances Prohibited From Use in Human Food; 21 CFR 190 Dietary Supplements; 21 CFR 219.80 Processes and Controls; 21 CFR 1030.10 Microwave Ovens; 21 CFR Subpart D – Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60 (d); 40 CFR 141 National Primary Drinking Water Regulations; 40 CFR 152 Subpart I – Classification of Pesticides; 40 CFR 152.175 Pesticides Classified for Restricted Use; 40 CFR 180.940 Sanitizing Solutions; 40 CFR 185 Tolerances for Pesticides in Food; 50 CFR 17 Endangered and Threatened Wildlife and Plants.

(ii) 7 USC 136(e) Certified Applicator, etc; Federal Food, Drug, and Cosmetic Act §201(s), (t) & (ff); Federal Food, Drug, and Cosmetic Act, 21 USC 301 (v); Federal Food, Drug, and Cosmetic Act, 21 USC 343; Federal Food, Drug, and Cosmetic Act §402; Federal Food, Drug, and Cosmetic Act §403(Q)(3)-(5); Federal Food, Drug, and Cosmetic Act §409; Federal Food, Drug, and Cosmetic Act §703; Federal Food, Drug, and Cosmetic Act §706; National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish; U.S. Public Health Service/FDA "Grade A Pasteurized Milk Ordinance"; “Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National

Conference on Interstate Milk Shipments", and "Methods of Making Sanitation Ratings of Milk Shippers"; United States Department of Agriculture/Agriculture Marketing Service "Milk for Manufacturing Purposes and its Production and Processing"; the International Plumbing Code; the USDA AMS 56 U.S. Standards, Grades, and Weight Classes for Shell Eggs; 50 FR 15861 United States Standards for Grades of Extracted Honey, 32 FR 7565 United States Standards for Grades of Comb Honey; Federal Meat Inspection Act (including the Wholesome Meat Act)/Poultry Products Inspection Act, Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282); and the Humane Methods of Slaughter Act 1978.

(iii) Regulations, rules, and other authorities listed in (i) and (ii) above which are in effect on January 1, 2015, are hereby adopted by the Wyoming department of agriculture and do not include any later amendments or editions. These documents are available for public inspection and may be purchased at cost from the office of the Wyoming department of agriculture.

(iv) Rules, regulations and other authorities adopted are readily available to the public and may be purchased from:

(A) The Code of Federal Regulations; http://bookstore.gpo.gov

(B) Federal Food, Drug & Cosmetic Act; United States Code; Federal Meat Inspection Act/Poultry Products Inspection Act; http://www.fda.gov/

(C) National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish; http://www.cfsan.fda.gov/~ear/nss3-toc.html

(D) Grade A Pasteurized Milk Ordinance, Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, Methods of Making Sanitation Ratings of Milk Shippers; http://www.fda.gov/

(E) Milk for Manufacturing Purposes and its Production and Processing; http://www.ams.usda.gov/dairy/prop_manufmlk.pdf

(F) International Plumbing Code; www.iccsafe.org

(G) USDA AMS 56 U.S. Standards, Grades, and Weight Classes for Shell Eggs; http://www.usda.gov

(H) 50 FR 15861 United States Standards for Grades of Extracted Honey; http://www.ams.usda.gov/standards/exhoney.pdf

(I) 32 FR 7565 United States Standards for Grades of Comb Honey; http://www.ams.usda.gov/standards/comhoney.pdf

(J) Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282); http://www.cfsan.fda.gov/~dms/alrgact.html

(K) Humane Methods of Slaughter Act 1978; http://www.access.gpo.gov/uscode/title7/chapter48_.html

CHAPTER 15

EGG GRADING REQUIREMENTS

Section 1. Licensing and Standardizaion

(a) In order to candle and grade eggs for sales to establishments, a license shall be applied for in accordance with Chapter 2, Section 2, (a) (ii) of this Rule.

(b) Standardization is required to ensure knowledge and consistency in candling and grading eggs and shall consist of the following:

(i) Upon receipt of the completed license application form and the license fee, an authorized representative of the Wyoming Department of Agriculture, Consumer Health Services Division shall provide a written and performance examination to the license applicant;

(ii) The written examination shall determine the license applicant's knowledge of egg quality and size standards established in this chapter;

(ii) The performance examination shall determine the license applicant's ability to candle and grade eggs; and

(iv) The license applicant shall obtain a grade of 80% or higher on the written examination and not exceed a deviation of ± 15% on the candling performance examination to qualify for an egg grader standardization.

Section 2. General Definitions

(a) The following definitions apply to this chapter of the Wyoming Food Safety Rule:

(i) “Candling” means the careful examination of the whole egg by means of a strong light in a partially dark room or place.

(ii) “Chalazas” a white structure that is continuous with the chalaziferous layer which suspends the yolk in the center of the white.

(iii) "Check" means an egg with a broken or cracked shell but with membranes intact and no leaking contents.

(iv) “Grader” means a person who determines the quality and size of eggs in accordance with Wyoming laws and rules through candling.

(v) “Haugh unit value” means the value resulting from the correlation of the height of the thick white when broken out as measured by a micrometer and the weight of the egg when broken out.

(vi) "Leaker" means an egg that has a crack or break in the shell and shell membrane to the extent that the egg content is exuding or free to exude through the shell.

(vii) "Loss egg" means an egg that is inedible, smashed or broken so that the contents are leaking, overheated, frozen, or contaminated.

Section 3. Eggs Deemed Unfit for Human Consumption

(a) Eggs defined and described in this section are deemed unfit for human food and may not be sold or offered for sale for human consumption.

(i) "Addled" or "white rot" means an egg that is putrid or rotten.

(ii) "Moldy" means an egg which has deteriorated so that mold spores have formed within the egg.

(iii) "Blood spot" is a spot of blood in excess of 1/8 inch (3.2 mm) in aggregate which adheres to the yolk of the egg.

(iv) "Black rot" means an egg which has deteriorated to such an extent that the whole interior presents a blackened appearance.

(v) "Blood ring" means an egg in which the germ has developed to such an extent that blood is formed.

(vi) "Adherent yolk" means an egg in which the yolk has become fastened to the shell.

(vii) "Incubated eggs" means eggs which have been subjected to incubation, whether natural or artificial, for more than 48 hours.

(viii) "Bloody white" means an egg with a general reddish appearance due to blood mixed through the albumen which may show spots of blood floating in the white.

(ix) "Meat spot" means that the egg has a speck of foreign matter adhering to the yolk or floating in the white.

(x) An egg that is smashed or broken and the contents are leaking.

(xi) Eggs which are otherwise unwholesome or adulterated as defined in 7 CFR 57 Inspection of Eggs (Egg Products Inspection Act).

Section 4. Sales of Checked Shell Eggs

(a) Checked shell eggs shall not be sold on or off premises to:

(i) Hospitals, institutions, nursing homes, convalescent homes, retirement homes, or schools, whether owned privately or by a governmental body;

(ii) Food establishments subject to licensing by the Wyoming Department of Agriculture, including but not limited to, bakeries, restaurants, cafes, drive-ins, and food processing plants; or

(iii) Private clubs, organizations, churches or church groups if members, the public and/or non-members and guests are served food.

(b) Checked shell eggs may be sold to a breaking plant approved by the department or for non-human food purposes to an animal-food processing plant in accordance with 7 CFR 57 Inspection of Eggs (Egg Products Inspection Act).

(c) Checked shell eggs may be sold on the premises to the end consumer only if conforming to the requirements of 7 CFR 57 Inspection of Eggs (Egg Products Inspection Act) and as follows:

(i) Each container of checked shell eggs sold or offered for sale shall have a label printed on the container, inserted into the container or by other means attached to the container advising the consumer that the eggs are being sold only for cooking and baking purposes where the cooking temperatures will reach or exceed 165°F. (73.9 C.). Each label must contain the words "checked shell" and the printing on each label shall be clean, clear and of such size print so as to be easily read by the consumer.

(ii) The label and/or container may not have on or in it any words, phrase or graphic material which might tend to mislead the purchaser or consumer that the eggs have been inspected by the department or that they have been candled or graded.

(iii) All references on the containers to size, grade, freshness and seals or imprint seals must be obliterated prior to sale to the consumer.

Section 5. Adulterating of Shell Eggs and Egg Products

(a) No person shall adulterate eggs or egg products except:

(i) Department-approved non-toxic substances or colorings may be added only to make them inedible for humans or for rechanneling eggs and egg products into an animal-food processing plant.

Section 6. Regrading Shell Eggs

(a) All eggs and egg products produced or sold in the state of Wyoming may be regraded by the regulatory authority in order to ascertain compliance with the rules contained in this chapter wherever they are produced, processed, held, kept, sold, offered or intended for sale.

(b) Eggs and egg products which do not comply with the rules contained in this chapter shall be ordered returned to the supplier by the regulatory authority. The supplier shall be notified why the eggs are being returned in writing by the regulatory authority.

Section 7. Candling Procedures

(a) The Wyoming standards for quality of shell eggs contained in this chapter only apply to eggs that are the product of the domesticated chicken hen and remain in the shell.

(b) Interior egg quality specifications for these standards are based on the apparent condition of the interior contents of the egg as it is twirled before the candling light. Any type or make of candling light that will enable the grader to make consistently accurate determinations of the interior quality of shell eggs may be used. The grader shall break-out an occasional egg and compare the broken-out and candled appearance to aid in correlating the candled and broken-out appearance by determining the Haugh unit value of the broken-out egg.

Section 8. Shell

(a) A "clean" shell is an unbroken shell free from foreign material and stains or discolorations that are readily visible. An egg may be considered clean if it has only very small specks, stains or cage marks, if such specks, stains or cage marks are not of sufficient number or intensity to detract from the generally clean appearance of the egg. Eggs which show traces of processing oil on the shell are considered clean unless otherwise soiled.

(b) A "dirty" shell is an unbroken shell which has dirt or foreign material adhering to its surface, has prominent stains, or has moderate stains covering more than 1/32 of the shell surface if localized or 1/16 of the shell surface if scattered.

(c) A "check egg" is an egg with a broken shell or crack in the shell, but with its shell membranes intact and its contents not leaking. A check egg is considered to be lower quality than a dirty egg.

(d) A "practically normal" (AA or A quality) shell is an unbroken shell that approximates the usual egg shape and is sound and free from thin spots. Ridges and rough areas that do not materially affect the shape and strength of the shell are permitted.

(e) An "abnormal" (B quality) shell is an unbroken shell that is somewhat unusual, decidedly misshapen, faulty in soundness or strength, or shows pronounced ridges or thin spots.

Section 9. Air Cell

(a) The "depth of air cell" (air space between shell membranes, normally in the large end of the egg) is the distance from its top to its bottom when the egg is held air cell upward.

(b) A "free air cell" is an air cell that moves freely toward the uppermost point in the egg as the egg is rotated slowly.

(c) A "bubbly air cell" is a ruptured air cell resulting in one or more small separate air bubbles usually floating beneath the main air cell.

Section 10. White

(a) A "clear" (AA, A quality) white is free from discoloration or from any foreign bodies floating in it. (Prominent chalazas should not be confused with foreign bodies, such as spots and blood clots.)

(b) A "firm" (AA quality) white is sufficiently thick or viscous to prevent the yolk outline from being more than slightly defined or indistinctly indicated when the egg is twirled. With respect to the broken-out egg, a firm white has a Haugh unit value of 72 or higher when measured at a temperature between 45°F. (7.2 C.) and 60°F. (15.6 C.).

(c) A "reasonably firm" (A quality) white is a white that is somewhat less thick or viscous than a firm white. A reasonably firm white permits the yolk to approach the shell more closely which results in a fairly well defined yolk outline when the egg is twirled. With respect to a broken-out egg, a reasonably firm white has a Haugh unit value of 60 up to 71 when measured at a temperature between 45°F. (7.2 C.) and 60° F. (15.6).

(d) A "weak and watery" (B quality) white is weak, thin and generally lacking in viscosity. A weak and watery white permits the yolk to approach the shell closely, thus

causing the yolk outline to appear plainly visible and dark when the egg is twirled. With respect to the broken-out egg, a weak and watery white has a Haugh unit value lower than 60 when measured at a temperature between 45°F. (7.2 C.) and 60°F. (15.6 C.)

(e) Eggs containing "blood clots and/or spots" which are small blood or meat spots (aggregating not more than 1/8 inch (3.2 mm) diameter) are to be classified as B quality.

(f) A "bloody white" is an egg, with a white which has blood diffused through it. Such a condition may be present in new-laid eggs. Eggs with bloody whites are classified as a loss.

Section 11. Yolk

(a) An "outline slightly defined" (AA quality) yolk is indistinctly indicated and appears to blend into the surrounding white as the egg is twirled.

(b) An "outline fairly well defined" (A quality) yolk is discernable but not clearly outlined as the egg is twirled.

(c) An "outline plainly visible" (B quality) yolk is clearly visible as a dark shadow when the egg is twirled.

(d) An "enlarged and flattened" (B quality) yolk is one in which the membranes and tissues have weakened and moisture has been absorbed from the white to such an extent that it appears definitely enlarged and flat.

(e) A "practically free from defects" (AA or A quality) yolk shows no germ development, but may show other very slight defects on its surface.

(f) A "clearly visible germ development" (B quality) yolk is one in which the development of the germ spot of a fertile egg has progressed to a point where it is plainly visible as a definite circular area or spot with no blood in evidence.

(g) "Blood due to germ development" is blood caused by development of the germ in a fertile egg to the point where it is visible as definite lines or as a blood ring. An egg having blood due to germ development is classified as inedible.

Section 12. Egg Quality Grades

(a) AA Quality:

(i) The shell must be clean, unbroken and practically normal;

(ii) The air cell may not exceed 1/8 inch (3.2 mm) in depth, may show unlimited movement and may be free or bubbly;

(iii) The white must be clear and at least reasonably firm so that the yolk is only slightly defined when the egg is twirled before a candling light; and

(iv) The yolk must be clear and firm.

(b) A Quality:

(i) The shell must be clean, unbroken and practically normal;

(ii) The air cell may not exceed 3/16 inch (4.8 mm) in depth, may show unlimited movement and may be free or bubbly;

(iii) The white must be clear and at least reasonably firm so that the yolk outline is only fairly well defined when the egg is twirled before the candling light; and

(iv) The yolk must be practically free from apparent defects.

(c) B Quality:

(i) The shell must be unbroken, may be abnormal and may have slightly stained areas.

(A) Moderately stained areas are permitted if they do not cover more than 1/32 of the shell surface if localized or 1/16 of the shell surface if scattered.

(B) Eggs having shells with prominent stains or adhering dirt are not permitted.

(ii) The air cell may be over 3/16 inch (4.8 mm) in depth, may show unlimited movement, and may be free or bubbly.

(iii) The white may be weak and watery so that the yolk outline is plainly visible when the egg is twirled before the candling light.

(iv) The yolk may appear dark, enlarged, and flattened, and may show clearly visible germ development but no blood due to germ development.

(A) The yolk may show other serious defects that do not render the egg inedible.

(B) Small blood spots or meat spots (aggregating not more than 1/8 inch (3.2 mm) in diameter) may be present.

Section 13. General Requirements for Buildings and Plant Facilities

(a) Plans and specifications shall be submitted to the Consumer Health Services inspector prior to beginning construction of the separate room or building for processing eggs.

(b) The building shall be constructed and maintained to prevent the entrance or harboring of vermin.

(c) Grading and packing rooms must be of sufficient size to permit installation of necessary equipment and the conduct of grading and packing in a sanitary manner.

(d) A toilet room is required for employees and shall be kept in a clean and sanitary condition.

(i) A hand sink shall be provided with hot and cold running water tempered by means of a mixing valve or combination faucet.

(ii) Toilet rooms must be vented to outside the building.

(iii) Signs instructing employees to wash their hands before returning to work shall be posted in the restrooms

(iv) All waste containers shall be of the covered type and be kept closed when not in use.

(h) Lights in the egg room/building shall either be shielded or utilize shatter proof bulbs.

(i) If mechanical equipment is used, adequate light must be provided for the detection and removal of stained and dirty shells and determining the condition of the packing material.

(i) The walls, floor and ceiling in the egg room or building shall be smooth, non-absorbent, easily cleanable and of a light color.

(j) The egg washing room may double as the egg grading and candling room if it can be adequately darkened to make accurate quality determinations of candled eggs.

(k) The candling lights shall deliver a reasonably uniform intensity of light at the candling aperture which will facilitate accurate quality determinations.

(l) Easily cleanable, certified scales shall be used to check the accuracy of weight classing.

(m) Adequate ventilation shall be provided.

(n) Cooler rooms shall have refrigeration capable of reducing and holding the maximum volume of eggs handled to a temperature of 45°F (7.2 C.) or below within 24 hours.

(i) A thermometer shall be conspicuously located in the refrigerated areas.

(ii) Cooler rooms shall be free from objectionable odors, dirt and pooled wastes.

Section14. Shell Egg Protecting Operations

(a) Shell egg protecting (oil processing) operations shall be conducted to avoid contamination of the product and maximize conservation of its quality.

(i) Eggs with excess moisture on the shell shall not be shell protected.

(ii) Oil that is obviously contaminated shall not be used in shell egg protection.

(iii) Processing oil that has been previously used or which has become contaminated shall be filtered and heat-treated at 180°F. (82.2 C.) for three (3) minutes prior to use.

(b) Shell egg processing equipment shall be washed, rinsed and treated with a bactericidal agent each time the oil is removed.

(i) Processing oil shall be filtered and heat-treated and shell egg processing equipment cleaned daily when in use.

(ii) Egg processing equipment shall be covered and protected against dust and dirt when not in use.

Section 15. Shell Egg Cleaning Operations

(a) Shell egg cleaning equipment shall be kept clean and in good repair and operating condition. It must be cleaned after each day's use or more frequently if necessary. Visible mineral deposits must be removed, either manually or by de-liming agents.

(b) Waste water from egg washing equipment shall be indirectly drained and wastewater from all drains shall drain to an approved sewage system.

(c) The egg room/candling and grading room shall contain a separate hand sink with hot and cold running water tempered by means of a mixing valve faucet.

(d) Facilities shall have means to wash, rinse and sanitize eggs in a sanitary manner.

(i) The water in continuous-type washers shall be completely changed as required and at least once during each shift and at the end of each shift.

(ii) The minimum maintained temperature of the wash water shall be 90°F. (32.2 C.) Pre-wetting by submersion may not exceed five (5) minutes.

(iii) Eggs shall be removed from the washing and rinsing area of the egg washer during rest periods and from the scanning area whenever there is a build-up of heat.

(iv) Only cleaning and sanitizing compounds approved by the department shall be used.

(v) The use of metered equipment for dispensing the compounds into solution is recommended.

(vi) The entire shell egg cleaning and drying operation shall be continuous and shall be completed as rapidly as possible.

(vi) Only potable water may be used to wash eggs.

(A) Water from a nonpublic water system shall be sampled and tested for coliform bacteria at least semi-annually.

(B) An analysis of the iron content of the water supply, stated in parts per million, is also required. An iron content of less than two (2) ppm is required.

(vii) All washed eggs must be effectively sanitized in warm, potable water which contains an approved sanitizing compound that is no less than fifty (50) ppm nor more than two hundred (200) ppm of available chlorine or it’s equivalent.

(viii) Washed eggs must be reasonably dry before cartoning or casing.

(e) Steam or vapors originating from the washing operation shall be continuously and directly removed to the outside of the building.

(f) Eggs that are to be transported to another location for sale shall be maintained at 45°F (7.2 C.) or colder during transportation.

Section 16. Packaging and Labeling

(a) The cartons used to package eggs shall be new and labeled with:

(i) Establishment name;

(ii) Establishment address;

(iii) Egg grade;

(iv) Safe handling instructions;

(v) Number of eggs in carton;

(vi) Packaging date; and

(vii) Wording “Keep Refrigerated”

(b) Cases and packaging material shall be visibly clean, free of mold, mustiness and off odors and shall be of sufficient strength and durability to adequately protect eggs during normal distribution.

(c) Every reasonable precaution shall be exercised to prevent eggs from sweating.

(d) The Wyoming certified grader’s number shall be stamped on the carton in a conspicuous location prior to entering commerce.

Section 17. Pesticides

(a) Pesticides, insecticides and rodenticides used in the plant must be approved by the department and shall be stored, handled and applied in accordance with the manufacturer's instructions.

Section 18. Health and Hygiene of Personnel

(a) No person known to have a communicable or infectious disease shall come in contact with eggs or egg products.

(b) Plant personnel coming in contact with eggs and egg products shall wear clean, washable clothing.

Section 19. Wyoming Grade and Weight Sampling Requirements for Shell

Eggs

(a) The grades provided below are applicable to edible shell eggs in "lot" quantities rather than on an "individual" egg basis. Reference in these standards to the term "case" means thirty (30) dozen eggs per case as used in commercial practices in the United States. A minimum of one hundred (100) eggs must be examined per sample case. For lots which consist of less than one (1) case, a minimum of fifty (50) eggs must be examined. If the lot consists of less than fifty (50) eggs, all eggs will be examined. Whenever grading service is performed on a representative sample basis, the sample shall be drawn and consist of not less than the minimum number of cases as indicated in the following table:

MINIMUM NUMBER OF CASES, RANDOMLY SELECTED, COMPRISING A REPRESENTATIVE SAMPLE

Cases in Lot	Cases in Sample
1	1
2 to 10 inclusive	2
11 to 25	3
26 to 50	4
51 to 100	5
101 to 200	8
201 to 300	11
301 to 400	13
401 to 500	14
501 to 600	16

(Include one (1) additional case for each fifty (50) cases or fraction thereof in excess of six hundred (600) cases.)

(b) Aggregate tolerances are permitted within each grade only as an allowance for variable efficiency and interpretation of graders, normal changes under favorable conditions during reasonable periods between grading, and reasonable variations of grader's interpretation.

(c) Substitution of higher qualities for lower qualities specified is permitted.

(d) "No grade" means eggs of possible edible quality that fail to meet the requirements of an official Wyoming grade or that have been contaminated by smoke, chemicals, or other foreign material which has seriously affected the character, appearance, or flavor of the eggs.

Section 20. Wyoming Consumer Grades and Weight Classes for Shell Eggs

(a) Grades.

(i) Wyoming grade AA.

(A) Wyoming consumer grade AA must consist of eggs which are 85% AA quality at origin. Within the 15% which may be below AA quality, not more than 5% may be B quality or checks in any combination. No dirties or loss eggs are permitted.

(B) Wyoming consumer grade AA must consist of eggs which are 80% AA quality at destination. Within the 20% which may be below AA quality, not more than 5% may be B quality, checks in any combination, and not more than 0.5% leakers or dirties in any combination.

(ii) Wyoming grade A.

(A) Wyoming consumer grade A at origin must consist of eggs which are 85% A quality or better. Within the 15% which may be below A quality, not more than 5% may be checks. No dirties or loss eggs are permitted.

(B) Wyoming consumer grade A at destination must consist of eggs which are 80% A quality or better. Within the 20% which may be below A quality, not more than 5% may be checks, and not more than 0.5°% leakers and dirties.

(iii) Wyoming grade B:

(A) Wyoming consumer grade B at origin must consist of eggs which are 85% B quality or better. Not more than 10% may be checks. No dirties or loss eggs are permitted.

(B) Wyoming consumer grade B at destination must consist of eggs which are 80% B quality or better. Not more than 10% may be checks and not more than 0.5% leakers and dirties.

(iv) Additional tolerances:

(A) In lots of two (2) or more cases:

(I) For grade AA:

(1.) No individual case may exceed 10% fewer AA quality eggs than the minimum permitted for the lot average.

(II) For grade A:

(1.) No individual case may exceed 10% fewer A quality eggs than the minimum permitted for the lot average.

(III) For grade B:

(1.) No individual case may exceed 10% fewer B quality eggs than the minimum permitted for the lot average.

(B) In lots of 2 or more cartons, no individual carton may contain less than 8 eggs of the specified quality and no individual carton may contain less than ten (10) eggs of the specified quality and the next lower quality. The remaining two (2) eggs may consist of a combination of qualities below the next lower quality (i.e., in lots of grade A, not more than two (2) eggs of the qualities in individual cartons within the sample may be checks.)

(b) Weight classes:

(i) The Wyoming consumer grades and weight classes for shell eggs are as indicated in the following table and shall apply to eggs sold by size.

Size or Weight Class	Minimum Net Weight Per Dozen	Minimum Net Weight Per 30 Dozen	Minimum Weight for Individual Eggs at Rate Per Dozen
	Oz (kgms)	Lbs (kgm)	Oz (gms)
Jumbo	30 (.85)	56 (25.4)	29 (.82)
Extra Large	27 (.77)	50 ½ (22.9)	26 (.74)
Large	24 (.68)	45 (20.4)	23 (.65)
Medium	21 (.6)	39 ½ (17.9)	20 (.57)
Small	18 (.51)	34 (15.4)	17 (.48)
Peewee	15 (.43)	28 (12.7)	--

(ii) A lot average tolerance of 3.3% for individual eggs in the next lower weight class is permitted as long as no individual case within the lot exceeds 5%.

INDEX

Using Dentition to Age Cattle

For many years, producers, veterinarians, and exhibitors (at cattle shows) have used cattle dentition to make general age determinations. Dentition will vary from herd-to-herd and animal-to-animal, because of the animal's genetics, their diet, and the varied geographical locations in which they are raised. Despite individual differences, when the age of an animal is not known, examination of the teeth serves as the best and most practical method of age determination. This document will serve as FSIS guidance for aging cattle. In order to age cattle using dentition, some background information is necessary. This document will discuss and demonstrate: types of teeth and their location in bovine jaws, deciduous incisors versus permanent incisors, eruption times for deciduous and permanent teeth, and using eruption times of permanent incisors to age cattle.

This cattle dental information is available at
http://www.fsis.usda.gov/About_FSIS/Technical_Service_Center/index.asp

Tooth Types and Location

There are three types of teeth found in the bovine: incisors, premolars and molars. Incisor teeth are found in the rostral portion of the mouth, but they are absent from the upper jaw. The premolars and molars (known as cheek teeth) are found in the caudal part of the mouth and are present in the upper (maxilla) and lower (mandible) jaws. The following schematic (Figure 1) of the bovine skull, from an older animal (all permanent teeth* are present), demonstrates the location of the teeth.

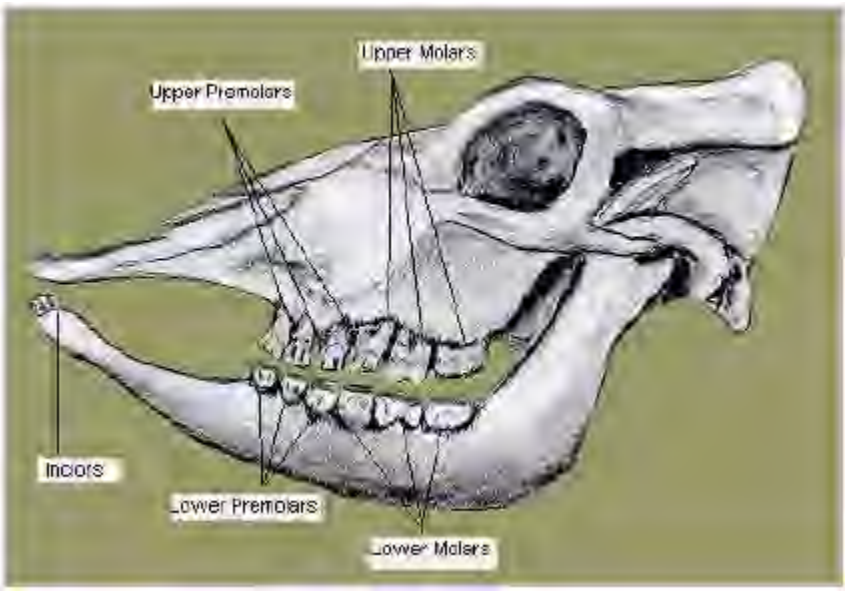


Figure 1

*At birth, calves have deciduous (temporary, milk, baby) teeth. The deciduous teeth are lost as the animal ages and they are replaced by the permanent teeth.

Deciduous (Temporary) Teeth

Calves have a total of 20 deciduous teeth. There are no deciduous molars and deciduous premolar 1 is not present. The dental formula for the deciduous teeth follows:

Deciduous teeth:
2(Di 0/4, Dc 0/0, Dp 3/3) = 20 deciduous teeth

The eruption of the deciduous teeth varies somewhat; about 75 percent of the well-bred calves have all incisors erupted at birth. Average periods of eruption of the deciduous teeth in cattle follow:

Table 1 – Eruption Times of Deciduous Teeth

Teeth	Age at eruption
First Incisor (Di* 1)	Birth to 2 weeks of age
Second Incisor (Di 2)	*
Third Incisor (Di 3)	*
Fourth Incisor (Di 4 or C)	*
First Cheek Tooth (Dp* 2)	Birth to a few days of age
Second Cheek Tooth (Dp 3)	*
Third Cheek Tooth (Dp 4)	*

* Di = deciduous incisor Dp = deciduous premolar

Photograph 1

In Photograph 1, the rostral view of a mandible from a young bovine demonstrates the location of the different deciduous incisors; they are identified – Di 1 through Di 4.

Permanent Teeth

Deciduous teeth are replaced by permanent teeth as the animal ages. Premolar 1 is not present. The dental formula for the permanent teeth of cattle follows

Permanent teeth:
2(I 0/4, C 0/0, P 3/3, M 3/3) = 32 permanent teeth

Average periods of eruption of the permanent teeth in cattle are found in the following table:

Table 2 – Eruption Times of Permanent Teeth

Teeth	Age at eruption
First Incisor (I* 1)	18 – 24 months
Second Incisor (I 2)	24 – 30 months
Third Incisor (I 3)	36 months
Fourth Incisor (I 4 or C)	42 – 48 months
First Cheek Tooth (P* 2)	24 – 30 months
Second Cheek Tooth (P 3)	18 – 30 months
Third Cheek Tooth (P 4)	30 – 36 months
Fifth Cheek Tooth (M 2)	12 – 18 months
Sixth Cheek Tooth (M 3)	24 – 30 months

* I = Incisor P = Premolar M = Molar

The photograph (Photograph 2) below shows a mandible from a cow with all of her permanent incisors present. The incisors are identified – I 1 through I 4.

Photograph 2

Note:
In addition to the simple numerical designations for teeth, the following terms are commonly applied to the individual incisors: central (Di 1 or I 1), first intermediate or middle (Di 2 or I 2), second intermediate or lateral (Di 3 or I 3), and corner incisors (Di 4 or I 4). Canine teeth are absent in cattle, unless

the fourth incisor (I 4), or corner incisor, is considered to be a canine tooth. If Di 4 or I 4 is considered to be a canine tooth, then the dental formulas change, slightly, to the following:

Deciduous formula:
2(Di 0/3, C 0/1, Dp 3/3) = 20 teeth

Permanent formula:
2(I 0/3, C 0/1, P 3/3, M 3/3) = 32 teeth

A dental formula is an abbreviated statement of the number and types of teeth found on one side of the top and bottom jaw. Because the dentition is the same on both sides of the jaw, the formula lists only one side, and is enclosed in parentheses and multiplied by 2 to arrive at the total number of teeth. Numbers above the lines are for the teeth located in the upper jaw and those below the line are for the teeth in the lower jaw.

Deciduous (Temporary) Incisors Versus Permanent Incisors

The deciduous incisors differ from the permanent incisors in being much smaller. The crowns (that part of the tooth that is covered with enamel) of the deciduous incisors are narrower then the permanent incisors and they diverge more from the base (at the gum line) of the tooth to the apex when compared to the permanent incisors. Photograph 3 compares the mandibles (lower jaws) from a young animal with deciduous incisors (red arrow) to an older animal with permanent incisors (white arrow). The difference in tooth size and shape and jaw width (and size) can be appreciated.

Using Teeth to Age Cattle

Cattle dentition is generally used as an indicator of age when actual birthdates are not available. Eruption times and wear of the teeth are the major factors used to estimate bovine age. This guidance document will base the aging of cattle on the eruption times for the permanent incisors.

The definition of eruption is the emergence/penetration/piercing of the tooth/teeth through the gingiva (the gum line).

Eruption of teeth in cattle typically follows the pattern shown in the Figures 2 - 7 below. The figures represent the incisor dentition from young animals through animals that are 30 months of age or older.

An animal 14 months of age would have a full set of deciduous incisors as shown in Figure 2. All four pairs of teeth are temporary and firmly in place. The teeth are short, broad and usually have a bright, ivory color. There is usually space between the Di 1 incisors. Other incisors may touch on the inside corner at the top of the tooth. As the animal ages, the deciduous teeth become loosely set in the jaw, especially the central 2 incisors. The teeth appear longer and narrower (Figure 3) than in younger animals and the teeth may or may not be touching at the upper corners; an animal with this dentition is approximately 15 – 18 months of age.

In Figure 4, a permanent central (I 1) incisor has erupted; temporary incisors may or may not be present when the permanent incisor erupts. The permanent incisors usually erupt at an angle (Figure 5) and straighten into a definite pattern with growth. In Figure 5, both central (I 1) incisors have erupted; they may or may not be in a straight line with the inside corners touching. The central incisors, in Figure 6, are in place, they have straightened and the inside corners are in line. Animals with eruption of one or more central incisors are considered to be 18 – 24 months of age. When one or both middle (I 2) incisors erupt, the animal is considered to be 24 – 30 months of age (Figure 7).

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Figure 7

Cattle 15 – 18 Months of Age

The following four photographs show a rostral (Photograph 4a and 5a) and rostrolateral (Photograph 4b and 5b) view of the dentition on the lower jaw. All deciduous incisors are evident. These temporary teeth are often loosely set in the jaw; especially the central incisors (Di 1). The animals are approximately 15 - 18 months old. In photographs 5a and 5b, the central incisors were very loose. Also, as described for Figure 2 above, the incisors are longer and narrower when compared to younger animals.

The following sets of photographs will demonstrate the aging of cattle, based on dentition, from 15 months to greater then 42 months of age. These animals were aged using Table 1 and Table 2 on the previous screens. The photographs will show a rostral view and at least one rostrolateral view of each set of teeth.

4a

4b

5a

5b

Cattle 18 – 24 Months of Age

The eruption of the first central incisor (or incisors) indicates that the animal is in the age range of 18 – 24 months as indicated in Table 2 above. The Di 1 deciduous incisors may or may not be present when the central incisors erupt.

The following three photographs show the eruption of the central (I 1) permanent incisors; the deciduous incisors have been lost. One incisor (white arrow), in photograph 6a, has recently erupted while the other incisor (red arrow) has been exposed, due to the gingiva being artificially torn during processing; this incisor had not penetrated the gum line. Photograph 6c gives a better view of the erupted incisor (white arrow).

6a

6b

6c

Cattle 18 – 24 Months of Age

These photographs (7a and 7b) show that the central incisors (I 1) have erupted and are fully developed, but are not in wear. The eruption of the central incisors indicates that the animal is in the 18 - 24 month age range. White arrows identify the central incisors in photograph 7a.

7a

7b

8a

8b

Cattle 24 – 30 Months of Age

Cattle that have the middle (I 2) incisor (or incisors) erupted are in the 24 – 30 month age range as indicated by Table 2 above.

However, FSIS, as written in FSIS Directive 6100.4 (see also Notice 5-04--this notice is expired and is available only as reference material) is using a conservative approach and is determining that cattle with eruption of a least one of the second set of permanent incisors (12) is 30 months of age or older. FSIS would consider the animal in photographs 9a – 9c to be 30 months of age or older; the animal in photographs 10a and 10b is also considered to be 30 months of age or older.

These three photographs (9a – 9c) show the eruption of the middle (I 2) incisors. The white arrows in photograph 9a locate the I 2 incisors; the central (I 1) incisors (found between the I 2 incisors) have erupted and are fully developed. Photographs 9b and 9c are rostro- lateral views of the lower jaw. These photographs demonstrate the variation in eruption of the I 2 incisors. The I 2 incisor (white arrow) in photograph 9c has recently erupted.

9a

9b

9c

Cattle 24 – 30 Months of Age

In photographs 10a and 10b, the central (I 1) and middle (I 2) set of incisors have erupted. The I 1 incisors are identified by the white arrows and I 2 incisors by the red arrows in photographs 10a and 10b.

10a

10b

Cattle Greater Than 30 Months of Age

The eruption of the lateral (I 3 or second intermediate) incisor (or incisors) indicates that the animal has reached 36 months of age. The eruption of the corner (I 4) incisor (or incisors) indicates that the animal has reached at least 42 months of age. These ages are based upon permanent incisor eruption times found in Table 2 on a previous screen.

The following 4 sets of photographs are representative of animals that are at least 42 months of age or older. These photographs (as you move from Photograph 11 through 14) also demonstrate that as cattle age the teeth are worn down. Photographs 14a and 14b demonstrate what happens after years of use; the teeth have worn down to what are called “peg teeth.”

11a

11b

12a

12b

13a

13b

14a

14b

Wyoming
DEPARTMENT OF Agriculture

Consumer Health Services

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

List of Requirements For State Inspected and Custom Exempt Slaughter and Processing Facilities

Contents

Slaughter and Processing Establishment Requirements

Slaughter Establishments

Retail and Custom Meat Exemptions

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Glossary

Amenable Species – This refers to any species regulated in the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA), which includes, but is not exclusive, beef, pork, goat, sheep, chicken, turkey, ratites, etc. Federal inspection is required for interstate sales. State or federal inspection is required for intrastate sales.

Bison – This species is classified as "exotic" and is considered a non-amenable species. For interstate or intrastate sales, either USDA or State inspection may be utilized. This species may also fall into the wild game category with the "free roaming" herd around northwest Wyoming.

Custom – This type of operation is "exempt" from inspection with limitations. An operation may provide a service of slaughtering and/or processing for the owner of that animal or product, without the benefit of inspection. This is allowed providing it is for the exclusive use of the owner in his/her household-by-household members or nonpaying guests. All custom products must be identified as "Not For Sale".

Federal – This type of operation slaughters and/or processes meat or poultry products under the inspectional supervision of the United States Department of Agriculture (USDA) employee. These products may be sold wholesale between any State, Territory or District of Columbia. These products may also be exported to other countries.

Food Animals – This term includes domesticated food animals such as cattle, swine, sheep, goats, rabbits, farm-raised deer, poultry (chickens, ducks, geese, turkeys, guineas, squab) and ratites. It also includes captive game animals, such as bison, whitetail deer and other animals of a normally wild type that are produced in captivity for slaughter and consumption and it includes captive game birds, which are farm-raised game birds, such as pheasants, quail, wild turkeys, waterfowl and exotic birds, which are produced in captivity for slaughter and consumption.

Interstate Meat & Poultry Sales – Amenble species must have federal inspection to be sold or shipped across state lines. Non-amenable species must have federal or state inspection to be sold or shipped across state lines. State or federal inspection is permitted with intrastate sales and shipping. As it stands, meat products may be posted on a web page to be sold, providing the product has been inspected. If a person orders a meat product from outside of Wyoming, and the product is an amenable species of the Federal Meat Inspection Act (FMIA), then the product must bear the **Federal** mark of inspection to be shipped. If the product is from a non-amenable species of the FMIA (ie: exotic species such as buffalo), then only **State** inspection is required for shipping. If the product is going to be shipped through the postal system, then the product must bear the **Federal** legend to cross the Wyoming State line. If the product is not going to cross the Wyoming State line, then **State** inspection is allowed.

Meat – Is the edible muscle and other edible parts of a food animal.

Meat Establishment – Is an establishment that is used to slaughter food animals for human consumption, or to process the meat of food animals for human consumption.

Mobile Custom Slaughter – Or mobile custom processing means custom slaughter or processing services provided at the recipient's premises, rather than at a meat establishment.

Non-Amenable Species – This refers to any species that is not regulated in the FMIA or PPIA, but falls under a voluntary inspection program. These species may include, but is not limited to, bison, rabbits, reindeer, etc. Non-amenable species may be sold interstate commerce with State inspection, whereas, USDA inspection is required for amenable species.

Retail Exempt – (Refer to pg 28 for further detail). This type of operation is "exempt" from inspection with limitations. An operation may obtain inspected meat and poultry products for further processing. When this processing occurs, the inspection is lost. However, the product may be sold retail from the establishment to home consumers. Single ingredient meat and poultry products may also be sold to HRI (Hotels, Restaurants and Institutions) provided they meet the retail exemption requirements.

Voluntary Inspection – In Wyoming, amenable and non-amenable species are treated the same. Therefore, inspection is required for the sale of any species of animal.

Wild Game Establishments – This type of operation is "exempt" from inspection with limitations. An operation may provide the service of processing wild game animals for the owner of that animal, without the benefit of inspection. The products produced from the wild game animal is for the exclusive use in the owner's household, members or nonpaying guests. Wild game is defined as any wild animal taken by means of hunting during a designated game season, such as deer, elk, mountain sheep, wild goat, antelope, moose or bear. This does not refer to operations that raise game animals on a farm or in confinement. Wild game products must be labeled with the name of species or identified as "Not For Sale".

Wyoming Intrastate Sales – The sale of any product within the State of Wyoming.

Wyoming State Inspected Establishments – This type of operation slaughters and/or processes meat or poultry products under the inspectional supervision of Wyoming Department of Agriculture Consumer Health Services employee. These products may be sold retail and/or wholesale within the boundaries of Wyoming.

Application Process

Approval

1. Approval from the department needs to be granted prior to opening for business (9 CFR 304.1). State plants must meet all of the following requirements and custom plants must meet the a.-i. requirements. These requirements include:
    a. Label Approval
    b. Floor plan and specifications
    c. Letters of guarantee
    d. Apply for food establishment license
    e. Inedible permit
    f. BSE/SRM SOP's
    g. Water & Sewage approval if on municipal supply
    h. Septic Approved
    i. Well approved and sampled
    j. Slaughter and/or processing days
    k. Grant of inspection
    l. Hours of operation
    m. SSOP Pre-requisite Plan
    n. HACCP Plan
2. Once all of the previous requirements have been met, approval from Consumer Health Services will be granted within a minimum of two weeks.

Design of Establishment

Layout

1. Determining the layout of the building, the placement of rooms and equipment, product flow and people traffic patterns are very important factors in designing an establishment.
2. A poorly designed establishment will affect your productivity, and result in congested operations that can lead to unsanitary conditions.

Flow of Operations

1. The flow or direction in which product moves within the plant is an important factor that can have an enormous influence on sanitation and the safety of finished products.
2. All raw meat and poultry products should be considered as potentially microbiologically contaminated and handled accordingly.
3. The flow of air and people should be just the opposite, moving from the cleanest areas progressively toward less clean areas.

Separation of Raw and Ready-to-Eat Product

1. Cross contamination of ready-to-eat product by raw products may occur if the layout does not provide for separation of these products.

2. Moving product from raw to final cooked product areas will reduce the risk of contamination along the way.
3. To prevent cross contamination in the preparation of products, the following are guidelines to consider:
    a. Exposed cooked product areas should be physically separated from other areas of the establishment.
    b. A ventilation system should be used to direct airflow away from exposed cooked product areas.
    c. Environmental control equipment such as fans and evaporator condensation pans should not be located above the product.
    d. Break rooms, dry storage, and maintenance areas should be separate, but adjacent to, the exposed cooked product rooms.
    e. Cooked product should be covered in rigid containers to protect it from contamination while in storage.
    f. Separate coolers and/or freezers should be available to use for exposed cooked product.

Vehicular Areas Outside the Building

1. Special care should be given in the design of vehicular areas outside your building, to prevent unsanitary conditions that might contaminate product in your establishment.
2. The following should be considered:
    a. Areas outside the building where vehicles are loaded or unloaded should be paved with concrete or a similar hard surface. Hard surface areas allow these areas to be kept clean and reduce the potential for water puddles or dust.

Construction

Materials

1. Care should be taken when selecting construction materials for the establishment.
2. The following are considerations that should be taken when selecting materials.
    a. Production and storage areas need to be constructed with materials that are readily and thoroughly cleanable.
    b. In order to be readily and thoroughly cleaned, building construction materials in production and storage areas must be:
        i. Rigid and durable
        ii. Non-toxic and non-corrosive
        iii. Impervious to moisture
        iv. A light, solid color such as white
        v. Smooth or textured with an easily cleaned, open pattern
3. Consider the following guidelines for selecting construction materials:
    a. In non-production and non-storage areas, building construction materials should be easy to thoroughly clean.

b. Special consideration should be given before using wood as a construction material.
c. Wood surfaces must not be exposed in areas where there is high moisture.
d. All wood surfaces in other areas must be sealed so they are resistant to staining, easily cleanable, and non-absorent.

Floors

1. Floors in areas where product is handled or stored should be constructed of durable, easily cleanable materials, and be impervious to moisture. Commonly used materials are concrete, quarry tile, brick, and synthetic material.
2. Floors should be installed and maintained to reduce the likelihood of cracks, depressions, or other low areas that would accumulate moisture.
3. Floors where operations are conducted should have a slip-resistant surface. Good results are obtained by using brick or concrete floors with abrasive particles embedded in the surface. Concrete floors should have a rough finish.
4. Floors should be sloped to avoid puddles or depressions within the slope where water will stand.

Coving/Curbs

1. Coving is used at the wall-floor juncture, column (post) floor juncture, and equipment support-floor juncture to provide a smooth transition for ease of cleaning and inspection.
2. Consider the following guidelines when using coving or curbs:
    a. Coving in production and storage areas should include the following criteria:
        i. All seams should be tight-fitting and sealed to eliminate all cracks and crevices, which may shelter insects, vermin and microorganisms.
        ii. The coving should eliminate any sharp angles that allow the accumulation of materials.
    b. Curbs should be provided to protect walls and wall finishes.
    c. Curbs should be high enough to protect the walls from pallets, trucks, or containers used in the establishment.
    d. Coving should be provided at the base of the curb.

Interior Walls Including Posts and Partitions

1. To prevent product from becoming contaminated by contact with interior walls, care needs to be taken in selection of materials for the finished surface of walls.
2. Consider the following guidelines when selecting a finish:

a. Interior walls in areas where product is stored or handled should be finished with materials that can be thoroughly cleaned and is impervious to moisture.
b. Examples are glazed brick, glazed tile, smooth concrete, and fiberglass reinforced plastic.
c. Walls should have a smooth texture, not one that is rough or uneven.
d. Fasteners for wall-covering material should be solid, smooth headed, and not have recesses, which allow the collection of foreign materials.

Ceilings

1. Ceilings in areas where product is stored or handled should be constructed to prevent the collection of dirt or dust that might sift through from the areas above or fall from overhead collecting surfaces onto equipment or exposed products.
2. It is recommended that ceilings and overhead structures be maintained free of sealing paint or plaster, dust, condensate, leaks, and other materials or defects.
3. Ceilings in areas where product is stored or handled should be constructed and finished with materials that can be thoroughly cleaned and are moisture resistant.
4. Examples of such materials are smooth concrete and fiberglass reinforced plastic.

Doorways and Types of Doors

1. Doors are barriers that allow the movement of product and people, but also present a barrier to contamination such as dirt, insects, and other vermin as well as the microbiological hazards that they carry.
2. The door type, construction materials and room in which the door is located are all important considerations when doors are installed in the establishment.
3. Doors are important in maintaining sanitary conditions especially in production and storage areas.
4. Consider the following guidelines for the most effective doors:
    a. They are impervious to moisture.
    b. They are high and wide enough to allow the movement of exposed product through the doorways without it coming into contact with the door or jamb.
    c. They are rigid and durable, and the junctions at jambs, walls, and floors are sealed to eliminate all cracks and crevices for debris, insects, and dirt to collect.
5. In selecting a type of door for your establishment, you need to consider the location of the door and whether or not product will be traveling through it.
6. Exterior doors used as exits need not be self-closing if they are:

a. Solid and tight-fitting;
b. Designated by the appropriate fire protection authority for use only when an emergency exists; and
c. Restricted so they are not used for entrance or exit from the building for purposes other than designated emergency exit use.

Ventilation

1. There should be enough ventilation for all areas of the establishment including workrooms, processing, smokehouse, packaging, and welfare rooms to ensure sanitary conditions.
2. A good ventilation system is important to the production of wholesome meat and poultry products.
3. Without controlling the quality of the air coming into the establishment, products may become contaminated with dust, insects, odors, or condensation.
4. The following should be considered when designing your ventilation system:
    a. The ventilation system should be designed so that turbulence is avoided. The longer the distance the air has to flow, the greater the resistance the air encounters not only from static air, but also from solid objects such as walls, equipment, people, and product.
    b. Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment, or utensils.
    c. Exhaust ventilation hood systems, which include hoods, fans, guards, and ducts, in food preparation and warewashing areas shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.
    d. To keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation should be used to bring in fresh air to areas where natural ventilation is inadequate.
    e. A good ventilation system should direct air flow away from exposed cooked product areas.
    f. Filters or other grease extracting equipment shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

Plumbing

Water System

1. If a private well is used to supply water to the facility, the information on the well and sample results (the state engineers office should have the information) shall remain on file.
2. If the facility is on a public water system, then a letter of verification from the city is needed.
3. The facility must meet the requirements of the Wyoming Food Safety Rule Chapter 8 and 9 CFR 416.
    a. Water must be distributed throughout the plant under adequate pressure and in quantities sufficient for all operating needs.
    b. Vacuum breakers (or a device in a water supply line, which opens when there is loss of pressure allowing air to enter to prevent back-siphonage or back flow) of an acceptable type shall be installed on all water or steam lines connected to various pieces of equipment throughout the plant.
    c. Municipal systems are sampled once per year and private systems are sampled twice per year by CHS staff.

Water Supply

1. Potable water shall be obtained from an approved source that is a public water system or a nonpublic water system that is constructed, maintained, and operated according to law (Wyoming Food Rule Chapter 8 Section 1-10).
2. Approved water systems shall be received from the source through the use of an approved public water main or one or more of the following that shall be constructed, maintained, and operated according to law:
    a. Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances.
    b. Water transport vehicles.
    c. Water containers.
3. A drinking water system that has had a seasonal shutdown or an extended period of disuse shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.
4. Water from a public water system shall meet 40 CFR 141 National Primary Drinking Water Regulations and water from a nonpublic water system shall meet the standards set by the Wyoming Food Rule.
5. Water from a nonpublic water system shall be sampled and tested at least semi-annually.
6. The most recent sample report for the nonpublic water system shall be retained on file in the establishment or processing plant.
7. Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water in

response to a temporary interruption of a water supply need not be under pressure.

8. Cross-connections are PROHIBITED and they may appear in many forms and in unsuspected places. Reversal of pressure and flow in the water system may be unpredictable. Plumbing cross-connections between a potable and non-potable water supply may constitute a serious public health hazard.
9. Once a cross-connection exists, any situation that causes a pressure differential with the potable line having the lower pressure can result in contamination of the entire water distribution system and potable water supply.
10. Some areas that you should consider providing some form of protection from backflow and back siphonage include the following:
    a. Water supply to pens for wash down or livestock watering.
    b. Water supply to compressor cooling systems, cooling towers, and boiler rooms.
    c. Water supply to cleanup systems, clean in place systems, etc.
    d. Water supply to hose connections.
11. Various mechanical anti-backflow devices are available to prevent backflow into a potable water supply system.
12. There are six basic types of approved devices that can be used to correct cross-connections, and they are:
    a. Air gap
    b. Barometric loops
    c. Vacuum breakers-both atmospheric and pressure type
    d. Double check valves with intermediate atmosphere vent
    e. Double check valve assemblies
    f. Reduced pressure principal backflow preventers
    g. Specific requirements concerning backflow can be found in local building and board of health codes.

Hose Connections and Hoses

1. There should be enough conveniently located hose connections with steam and water mixing valves or hot water connections provided throughout the establishment for cleaning purposes.
2. Hose connections are important in promoting routine cleaning of the establishment.
3. Consider the following guidelines when determining how many hose connections, location of hose connections, and storage of hoses:
    a. The number of hose connections depends on the number of drains.
    b. If a shut-off nozzle is provided on the hose after the hot and cold water-mixing valve, the vacuum breaker at the hose connection to the mixing valve will not work.
    c. Vacuum breakers should be installed on the hot and cold water supplies prior to the mixing valve to prevent such problems.

d. Hose connections should be provided with vacuum breakers to prevent back siphonage.

Floor Drains

1. All parts of floors where operations are conducted should be well drained.
2. There are two basic types of drains, point drains and trench drains.
    a. Point drains (most commonly used) are located in strategic points in the room with the floor sloped toward the drain. The wastewater flows over the surface of the floor until it reaches the drain.
    b. Trench drains involve a trough or trench that collects the waste from a larger area and directs the flow to a drain opening. The flooring is sloped toward the trench.
3. The location of floor drains depends upon many factors such as the type of task conducted in the space, the geometric shape of the area drained and equipment locations.
4. Floor drains should not be located under equipment because it makes them inaccessible to cleaning
5. Each floor drain should be equipped with a deep seal trap and vented properly to the outside.
6. All drainage lines must comply with local code requirements. They should be installed and maintained to be leak proof.
7. Secure drain covers, in addition to keeping out pests, also serve to prevent blockage of the traps and drainage lines with product scraps or other material too large to flow freely.
8. Cleanouts should be installed in the drainage system to prevent sewer blockages.
9. The following guidelines should be considered when installing cleanouts:
    a. Cleanouts should be located so they are readily accessible, and can be used without constituting a threat of contamination to edible products.
    b. To help avoid water puddling, cleanouts should be located on the "high lines" of floor slopes and away from traffic patterns.

Slaughter and Processing Establishment Requirements

Hazard Analysis Critical Control Point (HACCP) plan

1. For each process and/or product produced in the plant a HACCP plan needs to be in place before opening. Refer to the Wyoming Food Safety Rule Chapter 10, 9 CFR 416.11-17 and 9 CFR 417. This includes:
    a. Sanitation Standard Operating Procedures (SSOP's)
    b. Standard Operating Procedures (SOP's)

c. Good Manufacturing Practices (GMP's)
d. Record logs
e. Record charts

2. HACCP Training is required for anyone that is developing and implementing their HACCP plan (9 CFR 417.7).

Floor Plans

1. The floor plans must be drawn to scale/dimension and include blueprints and specifications (9 CFR 416.1 – 416.6)
    a. They must show equipment location including
        i. Truck-ways and any overhead railing
        ii. Material used on the floors, walls and ceilings
        iii. Slope of floors to floor drains
        iv. Plumbing detail including back flow prevention devices and cleanup hose connection shall be provided.

Equipment

1. Equipment and materials should comply with the Wyoming Food Safety Rule for direct food contact.
2. Equipment and utensils used for handling and preparing edible product or ingredients in any official establishment should be easily cleanable so that it will not be a source of contamination.
3. The following guidelines should be considered when selecting equipment:
    a. All direct product contact surfaces should be smooth and maintained free of pits, cracks, crevices, scale and rust, they should be corrosion and abrasion resistant, non-absorbent, shatterproof, nontoxic, and not capable of migrating into food products.
    b. Equipment should not be painted on areas in or above the direct product contact area.
    c. Construction materials that are sources of contamination and are prohibited include cadmium, antimony or lead as plating or the plated base material. Lead exceeding five percent in an alloy, enamelware or porcelain used for handling and processing product is prohibited.
    d. Equipment should be designed and installed in such a way that foreign materials, such as lubricants, heat exchanger media, condensate, cleaning solutions, sanitizers and other nonfood materials, do not contaminate food products.
    e. Equipment is self-draining or designed to be evacuated of water.
    f. Clean-in-place equipment should have sanitation procedures that are as complete and effective as those for cleaning and sanitizing disassembled equipment.

Slaughter

1. Any commercial equipment that is intended for use in an inspected facility shall meet the requirements of the Wyoming Food Safety Rule, Chapter 4 and Chapter 6, 9 CFR 317.20-21 and 9 CFR 416.1 – 416.6.
    a. All equipment must be smooth and easily cleanable as well as maintained in good working order.
    b. An approved head wash and head inspection rack will be made available for inspection purposes (9 CFR 307.2c-d).
    c. An approved hand-washing sink equipped with hot and cold running water and stocked with soap and paper towels shall be available (9 CFR 307.2m3). More information in the Sink section.
    d. An approved knife sterilizer, which is large enough to sterilize the entire food contact surface of the largest knife or saw being used, shall be available (9 CFR 307.2f).
    e. Other equipment
        i. Cradle
        ii. Splitting saws
        iii. Hoist and chains
        iv. Rail height
            1. Top of rails must be 11 feet from the floor for beef halves
            2. Hoists must be 16 feet from the floor
            3. Rails must be at least 2 feet from the walls
        v. Viscera cart with examination table
        vi. Elevated stands with handrails

Processing

1. Any commercial equipment that is intended for use in an inspected facility shall meet the requirements of the Wyoming Food Safety Rule, Chapter 4 and Chapter 6, 9 CFR 317.20-21 and CFR 416.1 – 416.6.
    a. All equipment must be smooth and easily cleanable as well as maintained in good working order.
    b. A certified scale must be used for all products sold by weight (9 CFR 317.20). Contact the Wyoming Department of Agriculture, Technical Services Division for details and a license.
    c. An approved hand-washing sink equipped with hot and cold running water and stocked with soap and paper towels shall be available and conveniently located (9 CFR 307.2m3). More information in the Sink section.
    d. An approved knife-sanitizer, which is large enough to sanitize the entire food contact surface of the largest knife or saw being used, shall be available (9 CFR 307.2f).
    e. Rail height

i. Top of rails must be 11 feet from the floor for beef halves
ii. Rails must be at least 2 feet from the walls

Coolers and Freezers

1. The facility must meet the requirements found in the Wyoming Food Safety Rule, Chapter 9.
    a. The floors, walls, and ceiling within the coolers/freezers shall be made of a smooth easily cleanable surface.
    b. They shall be constructed to accommodate the needs of the facility while maintaining sanitary conditions.
2. Coolers and freezers shall be large enough to meet the needs of the operation.
3. Coolers shall have an adequate number of floor drains.
4. Product should be stored in a manner that will eliminate conditions that may lead to contamination of product.
5. The following guidelines will help in preventing contamination:
    a. Coolers and freezers, including doors, should be constructed of materials that can readily and thoroughly cleaned, durable, rigid, impervious to moisture, non-toxic, and non-corrosive.
    b. Freezer doors should be constructed and installed to seal tightly to prevent accumulation of frost.
    c. Coolers and freezers should be equipped with floor racks, pallets or other means to ensure protection of product from contamination on the floor.

Restrooms

1. The facility must meet the requirements of the Wyoming Food Safety Rule Chapter 8 section 47-61.
    a. At least one toilet and not fewer than the toilets required by the Uniform Plumbing Code, as amended, shall be provided.
    b. They shall be completely enclosed and provided with a tight fitting, self-closing door.

Sinks

1. The facility must meet the requirements in the Wyoming Food Safety Rule Chapter 8 and 9 section 15.
    a. All prep and clean up sinks must be plumbed with an indirect drain.
    b. A three-compartment sink with drain boards, utensil racks, or tables on each end shall be provided for utensil/equipment cleaning and sanitizing.
    c. A separate sink is required for any food preparation.
    d. Hand washing sinks shall be installed to allow convenient use by employees in food preparation, food dispensing and ware washing areas and in bathrooms.

e. Hand sinks in establishments shall be provided with hot and cold water tempered by means of a mixing valve or combination faucet, have soap, and single use towels and must be foot or knee operated.
f. A utility or service sink must be installed in facilities not equipped with adequate floor drains.

Sewage Disposal

1. Use of a septic system requires a letter of approval from the Department of Environmental Quality or local authority that the system will handle the intended use.
2. There needs to be efficient drainage and plumbing systems that are appropriately sized, installed and maintained for the prompt removal of liquid and suspended solid wastes from the processing environment.
3. Drainage lines should be located so that if leakage occurs, it will not affect product or equipment.
4. If connected to a city sanitary sewer system, a letter from the city stating disposal of this kind of waste is approved.
5. The facility must meet the requirements of the Wyoming Food Safety Rule Chapter 8 and 9 CFR 416.1 – 416.6.
    a. Soil lines from the toilet bowls or urinals may not be connected with other drainage lines in the plant and may not discharge into a grease trap.
    b. All parts of floors where wet operations are conducted should be well drained.
    c. One drainage inlet should be provided for each 400 square feet of floor area and the required slope is ¼ inch per foot.
    d. Floor drains must be installed in carcass or drip coolers for easy clean up.
6. Sewage, one of the most dangerous sources of human pathogens, should never be allowed to come into contact with products, equipment, utensils or any food contact surfaces.
7. When installing an establishment sewage treatment facility, consider the following guidelines:
    a. The system should be large enough to handle the amount of sewage that the establishment produces and accommodate future increases.
    b. If a private septic tank, pretreatment, or treatment system is used it should be designed and operated to prevent contamination of products.

Rail Arrangement

1. To prevent contamination of carcasses, rails should be arranged to provide enough room for carcasses to move without touching equipment, walls, columns, other fixed parts of the building, and other carcasses.

2. The following guidelines should be considered when arranging rails in your establishment:
    a. Consideration should be given to the type of rail and the rail speed when determining how rails are to be arranged.
    b. Trim rails should be located prior to the carcass inspection station.
    c. To prevent the carcass from becoming contaminated by debris on the floor and from splashes during cleanups, the cooler rails should provide for clearance from the lowest part of the carcass to the highest point of the floor.
    d. A room or area for washing gambrels, hooks, and trolleys should be provided.

Lighting

1. Adequate, well-distributed artificial lighting is required in all places where natural lighting is insufficient (9 CFR 307.2m2).
    a. The overall intensity of artificial illumination should be no less than 30 foot-candles.
    b. In all areas where inspections are made, the intensity shall be no less than 50 foot-candles.
2. Light fixtures in all food preparation, storage, and utensil washing areas shall be shielded or utilize shatterproof type bulbs (Wyoming Food Safety Rule Chapter 9 section 16 & 17 and 9 CFR 307.2m2.
3. Lighting is critical to maintaining a sanitary environment for slaughter and processing operations. Without adequate lighting, unsanitary conditions are often difficult to see and correct.
4. When selecting and installing lighting systems, consider the following requirements:
    a. Light fixtures in rooms where exposed meat or poultry is handled must be shielded or utilize shatterproof bulbs to preclude contamination of products with broken glass. Light fixtures should be designed to prevent the collection of dirt, product, and debris on lamp surfaces.
    b. Lighting must be intense enough to allow both the establishment and inspection personnel to see unsanitary conditions and product contamination.

Meat Storage

1. The facility must meet the requirements found in the Wyoming Food Safety Rule Chapter 3.
    a. Adequate refrigeration facilities are required for all meat/food products. A temperature of 41ºF is required for product storage.
    b. Plastic strip doors are NOT approved in exposed product areas.
    c. All products must be stored to prevent cross contamination.

d. A working thermometer must be placed in each cold storage unit.

Non-Meat Storage

1. Packaging materials and ingredients should be stored in a sanitary environment to eliminate or reduce conditions that may lead to contamination of product.
2. Adequate storage facilities are required for all non-meat storage items including spices, paper products, utensils, etc.
3. All items must be properly labeled and protected from contamination and should not be stored on the floor.
4. The following are guidelines that will help in designing a dry storage area:
    a. Dry storage materials should be stored in a room dedicated to dry storage only.
    b. All meat or poultry ingredients and/or packaging materials must be stored in closed containers on racks or pallets and should not be stored on the floor.

Packaging and Label Approval

1. The facility must follow all label requirements that are found in the Wyoming Food Safety Rule Chapter 7 and 9 CFR 317.
    a. All labels with the inspection legend must have a completed and signed WDA label approval form on file.
    b. The safe handling statement is required on all raw meat products regardless of the inspection legend.
    c. Packaging materials, non-meat ingredients, and chemicals must have letters of guarantee on file.
    d. A "custom, not for sale" label shall be applied to each package of custom and wild game meat.

Inedibles

1. The facility must meet the requirements of 9 CFR 314.1 – 314.11.
    a. All condemned materials must be denatured.
    b. A separate and distinct area with sufficient ventilation shall be provided to house all inedible products before disposal or before being picked up for rendering.
    c. The area must be completely closed off to all edible product areas.
    d. Inedible barrels must be properly labeled, leakproof, and maintained in a sanitary manner. They must not be used for any other purpose

Denaturant

1. Condemned carcasses, parts or other products must be destroyed in the presence of an inspector.

2. Approved methods are incineration or a commercial denaturant may be used (9 CFR 314.3).

Sampling

Slaughter Facilities

1. Based on the types of animals slaughtered in the plant the operator should consult with their inspector for more information on the required sampling procedures.
2. Facility Responsibility
    a. *E. coli* carcass swabs (9 CFR 310.25a)
        i. A total of 13 samples are collected each year starting in June and ending in August.

Processing Facilities

1. Based on the processes in the plant, the following is a basic list of samples collected for product analysis per 9 CFR 318.9 and Directive 10,230.2.
2. Facility Responsibility
    a. *Listeria monocytogenes* swab (9 CFR 430 and Directives 10,240.2 and 10,240.4)
        i. The facility will collect swabs of the food contact surface (FCS)and non-food contact surface.
        ii. Samples will be taken on ready-to-eat product equipment according to *Listeria* compliance guidelines.

Chemicals

1. The facility must meet the requirements of the Wyoming Food Safety Rule, Chapter 7, section 17, and Chapter 9, section 27.
    a. All chemicals must be approved.
    b. Toxic items such as insecticides, rodenticides, caustics, cleaning items, and medicines shall be stored separately from any food or food contact utensils.
    c. An approved chemical list shall remain on file to be reviewed annually.
    d. If 180°F water is not available in the processing portion of the plant, approved chemical sanitizer must be used on all equipment and utensils.

Rodent and Insect Control

1. The facility must meet the requirements of the Wyoming Food Safety Rule Chapter 8 and 9 CFR 416.2a.
    a. Effective means should be provided to exclude rodents and insects.
    b. Only approved rodent and insects controls shall be utilized.

c. A diagram of the facility with locations of traps or glue boards shall remain on file.
d. Surveys shall be conducted on a routine basis.

2. To prevent drainage lines from becoming entrances into the plant for pests, including rats and mice, all lines must be equipped with effective rodent screens.
3. If windows and doors are kept open for ventilation they must be screened to protect against the entry of insects and rodents by:
    d. Sixteen (16) mesh to one (1) inch (16 mesh to 25.4 mm) screen.
    e. Properly designed and installed air curtains to control flying insects.
    f. Or other effective means.

Outside Premises

1. The facility must meet the requirements of the Wyoming Food Safety Rule Chapter 8 section 63-86 and 9 CFR 416.2a.
    a. The outside premises shall be maintained free of litter and unnecessary material.
    b. All rodent harborage including weeds and bushes shall be removed and maintained throughout the year.
    c. The garbage area shall be properly located and maintained in a sanitary manner.

Transportation Vehicles

1. Delivery vehicles must be clean and maintained in a sanitary manner.
2. All transportation or delivery vehicles must meet temperature guidelines for the product being transported.

Employee Health

1. The facility shall follow the personal hygiene required according to 9 CFR 416.5, the HACCP plan, and the Wyoming Food Safety Rule.
2. Occupational Safety and Health Administration requirements can be obtained from the Occupational Safety and Health Administration office at 307-777-7786.

Wyoming Food Safety Rule

1. In addition to federal meat plant requirements, equipment and food safety need to meet the requirements of the Wyoming Food Safety Rule.
2. A copy of the Wyoming Food Safety Rule can be obtained from:
    Consumer Health Services
    2219 Carey Ave.
    Cheyenne, WY 82002
    (307) 777-7211

3. It can also be viewed online at http://wyagric.state.wy.us/chs/contact.htm
4. A copy of the Code of Federal Regulations, Title 9 Parts 200-end can be purchased from:
   Superintendent of Documents
   US Government Printing Office
   Washington D.C. 20402
5. It can also be viewed online at http://www.fsis.usda.gov/OPPDE/rdad/publications.htm

Slaughter Establishments

Slaughter Area

1. The slaughter area is one of the most difficult areas to keep sanitary because of the nature of slaughter operations.
2. The following guidelines should be considered when designing and constructing slaughter areas to minimize contamination of carcasses:
   a. The slaughter area should be separated from the outside by a full height partition or wall made of impervious material.
   b. Any doors to the outside of the slaughter area should be self-closing to minimize the risk of contamination, including contamination by vermin.
   c. Slaughter areas should have floor space arranged to facilitate the sanitary conduct of operations and efficient inspection. For example, to prevent contamination of carcasses, sections through which products are moved from the slaughter area to rooms such as the offal cooler, should be located so that the material is not moved beneath rails from which dressed carcasses and products are suspended.

Ante-mortem Inspection Areas

1. Ante-mortem inspection areas should be designed and constructed to facilitate inspection and to prevent animals from being injured.
2. The following guidelines should be considered when designing and constructing these areas:
   a. To avoid delays in slaughter operations, pens for ante-mortem inspection should have the capacity for holding the maximum number of animals of the various species that will be slaughtered in a single day.
   b. To facilitate the ante-mortem inspection of animals, a separate suspect pen with a squeeze chute should be provided, where the temperature of the animals may be taken.
   c. At least 50 percent of the livestock pen, including the area where the suspect pen and squeeze chute are located, should be under a weather tight roof to provide an area for proper ante-mortem inspection in inclement weather.

Bovine Spongiform Encephalopathy(BSE)/ Specified Risk Material (SRM)

1. Plant's BSE/SRM Standard Operating Procedure (SOP) forbids the slaughter of non-ambulatory disabled cattle based on the Federal Register and the Interim Final Rule.
2. Plant's BSE/SRM Standard Operating Procedure addresses the control of SRM of beef animals during stunning. The use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle is prohibited.
3. Plant's BSE/SRM Standard Operating Procedures addresses the control of SRM of beef cattle by the identification and age classification of the animal through producer records OR dental examination according to FSIS Notice 5-04.
4. Cattle ≥ 30 months of age will follow slaughter procedures and proper carcass handling procedures according to plant's BSE/SRM Standard Operating Procedures, FSIS Notice 4-04 and 5-04, and 9 CFR 310.22.
5. Each plant that receives boxed beef from an outside source shall receive a "Letter of Guarantee" from the supplier. The letter must state that the beef is ≥ 30 months or < 30 months of age or state the Specified Risk Materials (SRMs) have been removed. The "Letter of Guarantee" shall be kept on file in the plant. Each supplier shall provide a "Letter of Guarantee" containing the above information.

Livestock Pens

1. In addition to preventing contamination of the slaughter area and minimizing contaminates on the hides of the animals, proper design and construction of livestock pens prevent injury to the animals. The facility must meet the requirements of 9 CFR 313.1 a, b
2. Consider the following facility guidelines when designing and constructing livestock pens:
    a. Livestock pens should be located outside the slaughter room to prevent contamination of products from dust, odors and other contaminates.
    b. If possible, the livestock pens should be separated from the slaughter room by full height partitions that are high and sturdy enough to prevent livestock from escaping.
    c. Gates, fences, and chutes should have smooth surfaces that are easily cleaned.
    d. Construction of livestock pens, unloading chutes, alleyways and ramps shall be paved (9 CFR 307.2a) and made so that they are easily maintained and kept in good repair.
    e. Pens shall be free of sharp or protruding objects, which could cause injury or pain to the animals and they must provide good footing for livestock. Waffled floor surfaces and cleated ramps are effective construction designs.
    f. Hose connections should be provided for cleanups.

g. Floors of the pens, ramps, unloading chutes, and runways should be sloped for drainage and cleaning.
h. To help prevent livestock from slipping and falling on floors covered with excess water, thereby further contaminating their hides, water troughs should be provided with overflows located above or adjacent to pen floor drains.
i. Driving of livestock shall be done with a minimum of excitement and discomfort to the animal. Livestock shall not be forced to move faster than a normal walking speed and prods and slappers shall be used as little as possible.
j. The pens should be large enough so that the animal can lie down and they shall have access to water at all times and if they are kept longer than 24 hours, they shall have access to feed (9 CFR 313.2).
k. All animals presented for slaughter in an official establishment shall undergo an ante-mortem inspection where the animal is examined and inspected the day of slaughter (9 CFR 309.1 and 9 CFR 309.18).

Stunning Area

1. Stunning areas, chutes and alleys, should be designed to prevent congestion, injury to animals, and minimize contamination of hides, which can lead to contamination of the carcasses.
2. The facility must meet the requirements and details that are listed in 9 CFR 313.15-16 and 9 CFR 313.10.
    a. Approved methods of stunning include:
        i. Mechanical
            1. Captive bolt
            2. Gunshot
        ii. Electric Current
3. The following guidelines should be considered when designing these facilities:
    a. The stunning area shall be designed and constructed to limit the free movement of animals sufficiently to allow the operator to locate the stunning blow with a high degree of accuracy.
    b. The stunning area shall also be designed to comfortably accommodate the kinds of animals to be stunned and must be free from pain producing features (9 CFR 313.1 and 9 CFR 313.15biii) such as restraining devices, sharp projections such as loose boards, exposed bolt ends, splintered or broken planking, protruding metal, and exposed wheels or gears.
    c. All pathways, chutes and alleys leading to stunning areas and the stunning area, should be free of unnecessary holes and openings where the animal's feet or legs may be injured.
    d. Overhead gates should be covered at the bottom edge to prevent injury to the animals.

e. Flooring should be constructed of roughened or cleated cement to reduce falls.
f. Stunning area should be provided for confining animals for stunning before bleeding.
g. If ritualistic slaughter operations are conducted in the stunning area, shackles to confine the animals also should be provided.
h. When captive bolt stunners are used, the stunning areas should be designed and constructed to limit the free movements of animals so that the operator can locate the stunning blow with a high degree of accuracy.

Dry Landing Area

1. A dry landing area large enough to accommodate stunned animals removed from the stunning pen should be provided adjacent to the stunning pen.
2. The following guidelines should be considered in designing and constructing this area:
    a. The area should allow enough room for the livestock.
    b. The dry landing area should be located and drained separately from the bleeding area.

Bleeding Area

1. To contain blood and prevent it from contaminating carcasses, a curbed bleeding area should be provided.
2. The following guidelines should be considered in designing and constructing this area:
    a. The bleeding area should be located so that the blood will not be splashed on stunned animals lying in the dry landing area or on carcasses being skinned on the cradle beds, if they are used.
    b. The curb around the bleeding area should be located far enough from the dressing bed or cradle to allow room for the carcasses to be maneuvered into the bed or cradle.

Facilities for Head Removal

1. To avoid contamination of the carcasses from rumen contents, facilities for head removal need to be carefully designed.
2. Head wash station should be provided for flushing and washing of heads.
3. A head inspection rack should be provided for inspection of heads.

Scalding

1. If a scalding tank is used to remove hair and other contaminants the following guidelines should be considered when installing a scalding tank:
    a. A mechanical exhaust fan above the scalding tank will disperse steam

Shaving, Singeing, and Carcass Washing

1. Singeing is done to remove hair.
2. If a polisher is used, water sprays to clean the carcass of hair should be provided.
3. To remove hair from the hide that was missed by the scalder and dehairing process, a carcass washer should be located at a point after completion of shaving operations and before the head dropper's station.

Viscera Trucks

1. In establishments with a limited rate of slaughter, viscera are usually placed in a specially designed hand truck for inspection.
2. The following guidelines should be considered for use of viscera trucks:
    a. For ease of cleaning, viscera trucks should be constructed of stainless or galvanized steel
    b. Viscera trucks should have an inspection pan and lower viscera compartment.
    c. When viscera trucks are used, a separately drained area should be available for washing and sterilizing such equipment.
    d. To prevent contamination of products, the washing facilities should be located at or near the point where inedible products are discharged from the trucks.
    e. When placed where splash might contaminate edible products, the truck washing area should have walls high enough to contain any splash.

Viscera Separation and Edible Byproduct Refrigeration

1. Because edible organs and parts (offal) originate at temperatures conducive to bacterial growth, care must be taken in providing facilities for separation of viscera and for refrigeration of edible byproducts to prevent them from becoming contaminated.
2. The following guidelines should be considered for holding edible byproducts:
    a. To prevent cross contamination, a separate cooler or separately drained part of a carcass cooler should be provided for holding edible organs and parts (offal) under refrigeration.
    b. To convey the edible byproducts to a cooler, a truck with removable metal drip pans should be provided.
    c. To prevent cross contamination, establishment and inspection personnel from the slaughter department should be able to access the edible byproduct cooler without passing through a line of carcasses or through a congested carcass cooler.

Foot Platforms

1. Foot platforms installed for establishment employees performing various carcass-dressing operations need to be carefully designed and installed to prevent contamination of carcasses.
2. The following guidelines should be considered:
    a. If elevated foot platforms are used, they should be located so they do not touch skinned portions of the carcass
    b. If stationary platforms are used, they should be set far enough away from the dressing rail to prevent contact with the forelegs of cattle.
    c. To provide space for operations and to prevent cross contamination by carcasses, rail stops on gravity flow rails should be spaced far enough apart to prevent contact between carcasses.

Carcass Washing

1. Special facilities for washing inspected carcasses are needed to remove bone dust and other contamination from the carcass.
2. The following guidelines should be considered when designing and constructing this area:
    a. A separately drained area or an area that is sloped to a floor drain should be provided where inspected carcasses are washed.
    b. If the carcasses are washed manually by establishment personnel, a platform should be provided to allow establishment personnel to be able to reach all parts of the carcass.

Marking and Branding

1. The facility must meet the requirements of the Wyoming Food Safety Rule Chapter 4 section 4 & 5 and 9 CFR 312 and 316.16.
    a. Only approved, food grade ink is to be used on carcasses.
    b. A stamp bearing, “Custom, not for sale,” is to be used on all non-inspected domestic carcasses.

Retain Room/Compartment

1. A retain room or compartment, or receptacle may be required by inspection.
2. Depending on the needs of inspection, consider the following guidelines for designing and constructing this room:
    a. The retain room or compartment must be equipped for locking or sealing.
    b. The room or compartment needs to be marked conspicuously “US Retained”.
    c. If the retain compartment is located in the cooler, the compartment should be separated from the remainder of the

cooler to prevent cross-contamination of inspected and passed carcasses.

d. The separation can be accomplished by creating a compartment constructed of partitions of corrosion resistant wire screen or flat expanded metal.

Office

1. State inspected plants should discuss with Consumer Health Service personnel the availability of space for the inspector and plant files.

Retail and Custom Meat Exemptions

Approval

1. All establishments that are retail exempt or custom processing shall follow and abide by Wyoming Food Safety Rule.
2. They shall follow the Rule on
    a. Construction
    b. Sanitation
    c. Labeling
    d. Humane Treatment of Animals
    e. Food Handling
    f. Personal Hygiene

Buffalo and Game Meat (Non-amenable Species):

1. The incoming product must possess the mark of inspection from an inspected meat processing/slaughter plant. Plants operating under federal inspection, Wyoming inspection, or another state's inspection program are acceptable.
2. There are no dollar limitations on the amount of buffalo and game meat that can be sold under retail exemption.
3. All other rules for retail exemption (listed above) also apply to non-amenable species.

Custom-exempt Slaughter and Processing

1. Slaughtering and processing services are provided for the animal's owner and the meat is for the owner's personal use only.
2. All sales transactions must be on a live-animal basis and must take place between the buyer and the seller prior to slaughter. The custom meat plant operator and the animal's owner cannot be involved in the sale of retail cuts, primals, or carcasses from animals slaughtered under custom exemption.
3. All carcasses, quarters, primals, and packaged products from the animals slaughtered under custom exemption must be labeled "not for

sale". Packaged meat must also display the custom processor's business name and address or town.

4. Slaughtering must take place in a licensed meat plant or on the animal owner's premises.
5. State-inspected slaughter plants may operate under custom exemption.
6. Custom-exempt processing plants may sell meat received from a federal plant or state inspected plant under retail exemption.
6. Plant's BSE/SRM Standard Operating Procedure (SOP) forbids the slaughter of non-ambulatory disabled cattle based on the Federal Register and the Interim Final Rule.
7. Plant's BSE/SRM Standard Operating Procedure addresses the control of SRM of beef animals during stunning. The use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle is prohibited.
8. Plant's BSE/SRM Standard Operating Procedures addresses the control of SRM of beef cattle by the identification and age classification of the animal through producer records OR dental examination according to FSIS Notice 5-04.
9. Cattle ≥ 30 months of age will follow slaughter procedures and proper carcass handling procedures according to plant's BSE/SRM Standard Operating Procedures, FSIS Notice 4-04 and 5-04, and the Code of Federal Regulations 310.22.

Labeling Requirements:

1. Product name
2. Net weight. Unit cost (price/lb) if it is a random weight package
3. Safe Handling Statement (raw product)
4. Ingredients on label or placard if product is pre-packaged
5. Business name/address
6. "Imported From (country of origin)" if the meat came from another country. Ground meat products are exempt from this rule.

Note: *retail-exempt labels on single or multi-ingredient pre-packaged products do not require formal label approval and should be reviewed and approved in-house by the plant's Consumer Health Specialist. The Wyoming Food Safety Rule, Chapter 4, should be referred to for complete labeling requirements of meat products.*

Selling meat under retail exemption:

1. The incoming product must come from a federal or Wyoming-inspected meat plant and is delivered to the retailer in packages, boxes, or carcasses with an inspection legend.
2. The finished product is sold to the final household consumer (single & multi-ingredient products). Mailing/shipping and sales to distributors or other retailers are not allowed.
3. The single-ingredient product is sold wholesale (HRI only) AND:

a. HRI meat sales (beef, pork and lamb) do not exceed 25% of total retail meat annual sales or $54,500 (this amount changes annually).
b. HRI poultry sales do not exceed 25% of total annual retail poultry sales or $45,800 (this amount changes annually).
c. HRI products must be properly labeled on the box and also each package

4. "Pass-through" HRI sales of any federally or state-inspected meat product in unopened boxes or packages with the mark of inspection are allowed. Dollar limitations do not apply to these products.
5. If the retailer is also a Wyoming state-inspected meat processing plant, all products made in this plant AND sold under retail exemption must NOT bear the Wyoming inspection legend.
6. If the retailer is also a Wyoming state-inspected slaughter plant, meat from inspected carcasses may be sold under retail exemption.

Out of State Products

1. If a person orders a meat product from outside of Wyoming, and the product is an amenable species of the Federal Meat Inspection Act (FMIA), then the product must bear the **Federal** mark of inspection to be shipped. If the product is from a non-amenable species of the FMIA (ie: exotic species such as buffalo), then only **State** inspection is required for shipping.
2. If the product is going to be shipped through the postal system, then the product must bear the **Federal** legend to cross the Wyoming State line.
3. If the product is not going to cross the Wyoming State line, then **State** inspection is allowed.

Equipment Pictures

1. Blood Trap

2. Brisket Saw

3. Carcass Splitting Saw

a. Pork Splitting Saw

b. Beef Splitting Saw

4. Cradle

5. Dehider

6. Gambrel Table

7. Hand Washing Sink (Foot Operated)

8. Head Inspection Truck

9. Head Washing Station

10. Hide Puller

11. Hind Leg Transfer Station

12. Hoist and Chains

13. Inspection Tables

14. Offal Cart

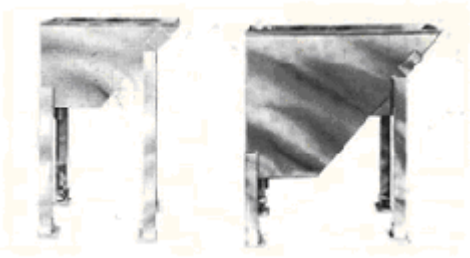
15. Platforms

a. Elevated Platform

b. Platform with Handrail

c. Low Platform

16. Saw Sterilizer



17. Three Compartment Sink (Indirect Drain)

18. Variety Meat Chilling Rack

FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from the Inspection Requirements of the Federal Meat Inspection Act

May 24, 2018

This guideline is designed to help firms that slaughter livestock or process meat and meat products determine whether they are exempt from required Federal inspection under the Federal Meat Inspection Act.

USDA-FSIS

What is the purpose of this guideline?

Many businesses are interested in slaughtering livestock or producing meat or meat food products but are not sure if they are required to operate under Federal inspection. This guideline explains each of the exemptions from inspection, when they apply, and which Food Safety and Inspection Service (FSIS) regulatory requirements must still be met.

Who is this guideline designed for?

This guideline is designed for any person or business seeking more information about the exemptions from the requirements for inspection by FSIS, or emerging business model operators that handle meat or meat food products that are exempt from inspection requirements. FSIS currently requires inspection, unless exempted, for meat or meat food products from cattle, sheep, swine and goats.

FSIS currently requires inspection, unless exempted, for meat or meat food products from cattle, sheep, swine, and goats.

This guideline will be especially useful for producers and businesses that are exempt from inspection by regulation:

- small and very small slaughter or processing establishments wishing to provide custom exempt services (see page 4) to owners of livestock;
- retail stores making sales directly to consumers at a single location or at satellite stores owned or operated by the retail store;
- restaurants selling or serving ready-to-eat (RTE) meals to individual consumers;
- caterers delivering or serving RTE meals to individual consumers;
- restaurant central kitchens sending RTE meals to their satellite restaurant locations or vending machines;
- businesses that are a combination of a retail store and a restaurant;
- internet advertisers, marketers, and brokers of meat or meat food products to consumers;
- firms using common couriers to transport meat or meat food products to consumers; and
- farmers wishing to engage in direct purchase agreements with school food service authorities for livestock slaughtered and prepared under State or Federal inspection.

This guideline reflects FSIS's policies and procedures and can be used now. However, FSIS is requesting comments on this guideline and may make changes to it based on comments.

How can I comment on this guideline?

FSIS seeks comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content,

readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name - FSIS, and document title: *FSIS Guideline for Determining Whether a Livestock Slaughter or Processing Operation is Exempt from the Inspection Requirements of the Federal Meat Inspection Act 2017.* Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Guideline for Livestock Exemptions**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Agency Issuances** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

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Introduction

Under the Federal Meat Inspection Act (FMIA), FSIS conducts inspection in all establishments where cattle, goats, sheep and swine are slaughtered or processed for sale as articles of commerce, unless an exemption from inspection applies. See page 23 for more about what is meant by "commerce." The USDA's Food Safety and Inspection Service (FSIS) is the public health agency responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS does this by verifying compliance with its regulations, found in 9 Code of Federal Regulations (CFR) 300-599. Daily inspection is provided by FSIS or by States that operate their own meat and poultry inspection (MPI) programs that are "at least equal to" FSIS's inspection program.

The FMIA exempts some slaughter and processing activities and operations from its inspection requirement. Those exemptions are found in 21 U.S.C. 623 and 661, and FSIS issued regulations on those exemptions (9 CFR 303.1). Facilities operating under an exemption are not exempt from the adulteration and misbranding requirements of the FMIA and may be subject to State or local regulatory requirements.

Note: Exemption guidance for poultry products can be found in Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act.

What requirements apply to persons, firms or corporations wishing to conduct business under the livestock inspection exemptions?

Although exempt from the daily inspection requirements, these exempt facilities remain subject to the access and examination provisions of the FMIA (21 U.S.C. 642). Therefore, business records, per 9 CFR 320.1, must be maintained and access to places of business and opportunity for examinations of facilities, inventory, and records must be provided to authorized FSIS personnel.

As is noted above, meat products exempt from inspection are not exempt from the adulteration or misbranding provisions of the FMIA. The adulteration and misbranding provisions of the FMIA can be found in 21 U.S.C. 601.

- A meat food product is adulterated if it
  - was prepared, packed or held under insanitary conditions;
  - is for any reason unsound, unhealthful, unwholesome or unfit for human food;
  - consists in whole or part of any filthy, putrid, or decomposed substance;
  - may have been rendered injurious to health; or
  - bears or contains any poisonous or deleterious substance which may render it injurious to health (i.e. undeclared allergen, chemical residue).
- A meat food product is economically adulterated when any valuable constituent, in whole or in part, has been omitted or removed, or in which a less valuable substance has been substituted.
- A meat food product is misbranded if its label is false or misleading, or if it does not contain the required labeling features.

Who determines whether an operation qualifies for an exemption?

There is no registration requirement with FSIS or approval process from FSIS to operate under an exemption. The person operating the business makes the initial determination and decides which, if any, exemption applies. However, FSIS Office of Investigation, Enforcement and Audit (OIEA) Compliance Investigators periodically verify whether the firm meets the relevant exemption requirements in 9 CFR 303.1.

For assistance in understanding the regulations applicable to exempt operations, please contact the FSIS Policy Development Staff at 1-800-233-3935 or submit your questions through askFSIS.

The person operating the business determines if he or she is qualified for an exemption.

FSIS OIEA Compliance Investigators may verify that the establishment meets the exemption requirements in 9 CFR 303.1.

What are the exemptions from USDA FSIS inspection?

The FMIA, in 21 U.S.C. 623(a), exempts from routine Federal inspection:

- Livestock slaughtered for personal use
- Livestock custom slaughtered or prepared

The FMIA, in 21 U.S.C. 661(c)(2), exempts from routine Federal inspection, operations of types traditionally and usually conducted at:

- Retail stores
- Restaurants
- Restaurant central kitchen facilities
- Caterers

Criteria and Notes for Each Exemption

A. PERSONAL USE

Mandatory inspection for the slaughter and processing of privately owned livestock is not required, provided the criteria below are met (21 U.S.C. 623; 9 CFR 303.1(a)(1)):

> (a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:
>
> (1) The slaughtering by any individual of livestock of their own raising, and the preparation by them and transportation in commerce of the carcasses, parts thereof, meat and meat food

products of such livestock exclusively for use by them and the members of their household and their nonpaying guests and employees.

Personal Use Criteria:

1. The resulting product from the animal slaughtered and processed under this exemption is exclusively for the private use by the:
    a. owner raising the livestock,
    b. members of their household,
    c. household nonpaying guests, or
    d. household employees.

2. The slaughter and processing of the livestock is performed by the owner of the livestock.

3. No livestock are slaughtered which are unfit for human consumption. Specified risk materials (SRMs)are inedible and prohibited for use as human food.

4. The carcass and parts are not prepared, packed, or held under insanitary conditions.

Personal Use Notes:

1. All of the criteria above must be met, otherwise, the livestock is not eligible to be slaughtered and processed under this exemption, and inspection is required.

2. There is no limit on the number of livestock that an owner may slaughter and process for their personal use.

3. A person may purchase livestock from a farm or ranch and then slaughter it onsite using the farm or ranch facilities or equipment.
    a. If a person purchases livestock, and uses the onsite facilities without assistance from the seller, then the activity remains personal use.
    b. If the seller participates in the slaughter or processing activity, then the facility owner is subject to the custom exempt criteria described below.

4. Personal use products, although uninspected, may move across State lines.

5. The owners of the livestock may or may not reside at the same physical location as the animal.

6. The exempt meat food products may not be sold or donated.

B. CUSTOM SLAUGHTER AND CUSTOM PROCESSING

A custom exempt operator slaughters livestock belonging to someone else and processes the carcasses and parts, for the exclusive use, in the household of that owner, by the owner, members of the owner's household, non-paying-guests, and employees. The custom exempt operator may also engage in the business of buying or selling other meat and meat food products, derived from State or Federal inspected sources.

A custom exempt operator may slaughter, or process custom exempt product, or do both. The owner of the livestock may opt to have his or her livestock slaughtered under the custom exemption by one

custom exempt operator, and then choose to have a second custom exempt operator do the processing. The owner of the livestock may also slaughter the animal and then have the carcass further processed at a custom exempt processing facility.

The applicable regulatory requirements are found in 9 CFR 303.1(a)(2):

> (a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:
>
> (2) The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock, exclusively for use, in the household of such owner, by the owner and members of their household and their nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of their own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by the owner and members of their household and their nonpaying guests and employees.

Custom exempt operations must result in meat and meat food products that are fit for human consumption.

Custom Slaughter and Custom Processing Criteria:

1. The resulting product from the animal slaughtered and processed under this exemption is exclusively for the private use of the:
    a. owner of the livestock;
    b. members of his the owner's household;
    c. nonpaying guests; or
    d. household employees.

2. Records of the names and addresses of the owner of the livestock and products must be kept by the custom exempt operator. The recordkeeping requirements of 9 CFR 320.1 apply to custom exempt operations.

3. No livestock are slaughtered which result in food unfit for human consumption.
    a. For reference, in official establishments non-ambulatory disabled cattle are considered unfit for human food and must be condemned, including those that become non-ambulatory after passing ante-mortem inspection (9 CFR 309.3). However, custom operators may slaughter for human food cattle that become non-ambulatory disabled after they are delivered to the custom slaughter facility if the operator of the facility does not observe any other condition that would render the animal unfit for human food (74 FR 11463, 11464).
    b. Field-dressed livestock (cattle, sheep, swine, goats) may be brought in for custom exempt processing. The custom exempt operator may ask the owner of any field-dressed cattle to provide a written statement that the animal was ambulatory at the time of slaughter. This statement helps to support that the beef products are safe, wholesome and unadulterated.

c. The facility must handle and maintain inedible material to prevent the diversion of inedible animal products (including SRMs) into human food channels, resulting in the adulteration of human food (9 CFR 303.1(a)(2)(i), 303.1(b)(4), 381.10(a)) (4), 416.2(b)(4), and 416.3(c)).
d. The regulation 9 CFR 303.1(b)(1) states that "exempted custom prepared products … shall not be adulterated as defined in paragraph 1(m) of the Federal Meat Inspection Act." Therefore, custom exempt product cannot contain SRMs, including the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle 30 months of age and older. The distal ileum of the small intestine and tonsils from all cattle are SRMs, considered inedible and, therefore, are not to enter the food supply (9 CFR 310.22). See FSIS Using Dentition to Age Cattle for more information.

4. Livestock must be slaughtered and handled in compliance with the Humane Methods of Livestock Slaughter Act.

5. The facility must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.
    a. The regulatory requirements of 9 CFR 416.1 to 416.6, except for 416.2(g)(2)-(6), apply to all custom exempt facilities.
    b. The additional regulatory requirements, including recordkeeping, of 9 CFR 416.12 to 416.16, apply to custom exempt operations that are conducted in an official establishment, 9 CFR 303.1(a)(2)(i).

6. The custom exempt product cannot be sold or donated as it is exclusively for the use by the owner in their household. Articles which are capable for use as human food, if not delivered to the owner, must be denatured or otherwise identified in accordance with 9 CFR 325.13, so as to be made distinguishable from human food, per 9 CFR 303.1(b)(4).

7. The carcasses and parts prepared on a custom exempt basis shall be marked as "Not for Sale," or if placed in immediate containers labeled with "Not for Sale," until delivered to the owner, per 9 CFR 316.16.

8. In a facility that hosts both an official establishment and an unofficial custom exempt operation, the custom exempt prepared livestock products must be kept separate and apart, per 9 CFR 303.1(a)(2)(ii), from any products that are for sale. Separation can be achieved by time or space. For example, the same cooler can be used to store both custom exempt products and inspected products. The custom exempt products are stored on separate rails or shelves and marked "Not for Sale," which makes them separate and distinct from the inspected product.

Custom Slaughter and Custom Processing Notes:

1. There is no registration requirement with FSIS or approval process from FSIS to operate under the custom exemption. FSIS recommends that operations that are exempt from FSIS inspection are appropriately permitted through the State and local (county, city) authorities. Check with those authorities for their applicable licensing requirements. FSIS will verify compliance with the FMIA statutory requirements, and 9 CFR regulatory requirements, annually.

2. There is no limit to the amount of livestock that an owner may slaughter and process for their personal use under the custom exemption.

3. If any of the eight criteria above are not met, the custom exempt operator may be ineligible for the exemption.

4. If the custom operations are conducted in a facility that also has an official USDA inspected operation, an owner's animal may be slaughtered under USDA inspection if so desired by the owner. After the animal passes both ante-mortem and post-mortem inspections, it can be returned to the owner, unless condemned. The animal should be kept separate throughout the process in order to be returned to the owner.

5. Selling livestock to a customer does not disqualify a business from the custom exemption. A custom exempt operator may sell livestock to a person(s) prior to slaughter and then custom slaughter the animal for the new owner. The custom exempt operator would be required, upon request, to provide records, per 9 CFR 320.1(a), that fully disclose the transfer of ownership prior to slaughter or processing of the livestock.

6. The operator of a custom exempt facility may also slaughter and process their own livestock for their exclusive consumption, or members of their household, nonpaying guests or employees, under the personal use exemption.

7. Selling livestock to a customer and then allowing that owner to use onsite facilities for the slaughter of the livestock still constitutes personal use slaughter. However, once the seller assists in the slaughter or processing, then the facility becomes a custom exempt facility, subject to 9 CFR 303.1(a)(b).

8. A custom exempt operation may use a mobile slaughter and processing unit.

9. The equipment used for custom exempt slaughter and processing must be thoroughly cleaned and sanitized prior to their use for preparing any inspected products, per 9 CFR 416.12(a), to prevent direct contamination or adulteration of product(s).

10. The risk of infection from Trichinae is increased in swine that have access to rodents and wildlife, such as pasture-raised, free-range and feral swine. All forms of fresh pork, including fresh unsmoked sausage, are customarily well cooked in the home by the consumer, and therefore the treatment of such products for the destruction of trichinae is not needed. However, in order to produce a safe, wholesome and unadulterated product, pork products that might be eaten rare or without thorough cooking because of the appearance of the finished product, may require treatment for the destruction of trichinae.

11. FSIS recommends, but does not require, that custom exempt operators keep production records of cooking and cooling of meat food products to support that they produce safe, wholesome, unadulterated products as required by the FMIA.

12. Any canned product from custom exempt livestock must be prepared in accordance with 9 CFR 318 Subpart G – Canning and Canned Products, including written processing schedules.

13. Although the items listed below are not specifically required by the HMSA, FSIS recommends the custom exempt operators:
    a. provide water and feed for animals in pens,

b. maintain facilities in good repair to prevent injury to animals,
c. drive the livestock with a minimum of excitement and discomfort,
d. separate disabled animals from ambulatory animals,
e. not drag disabled animals while still conscious, and
f. handle animals in accordance with applicable state and local laws.

14. If an owner of the livestock wishes to transport custom exempt product from one custom exempt facility to another for further processing, they may do so. (The product must be marked "Not for Sale" during transportation, per 9 CFR 303.1(a)(2)(iii).)

15. Commingling of fat trimmings and meat trimmings from custom exempt animals to facilitate rendering or sausage production is allowed with each owner's written consent. All of the resulting commingled product must be clearly marked "Not for Sale." See FSIS Directive 5930.1, Custom Exempt Review Process, page 9, for more information.

16. There may be more than one owner of the live animal. Sharing a live animal is acceptable provided proof of ownership of the live animal is available, upon request to the custom exempt operator, for Agency review.

17. The custom exempt operator must maintain records showing the identity of the individual owners' names prior to slaughter. In the case of more than one owner of the livestock, a list of the individual owners' names is required prior to slaughter, per 9 CFR 303.1(b)(3).

18. Carcasses and other products of custom slaughter are not eligible to be sold. Therefore, sale or purchase of the live animal using the services of a custom exempt operator would be based on live weight, price-per-head, or other quantity pertaining to the live animal. The custom exempt operator can only charge the owner a service fee for the livestock slaughtered or prepared on a custom basis, not for the meat food product itself which is derived from the custom slaughter or processing because the custom exempt operator does not own the live animal nor the resultant product.

19. The custom exempt operator can arrange the purchase of a live animal for a customer, conduct the subsequent slaughter and processing, and arrange the delivery of the "Not for Sale" product to the owner because the FMIA does not preclude the custom exempt operator from acting as an agent on behalf of the livestock owner. The custom operator would be required, per 9 CFR 303.1(b)(3), to provide the name and address of the owner prior to custom slaughter.

A retail store's sales could consist solely of orders placed by the consumer via fax, phone, or online, and shipped from the retail store.

C. RETAIL STORES

The FMIA and meat inspection regulations provide a retail store exemption for businesses that further prepare meat and meat food products for sale to consumers. Traditionally, a retail store in the 1970s, when the 9 CFR 303.1(d) regulations were implemented, consisted of a physical brick-and-mortar store. It typically included a butcher counter, where consumers could buy steaks, chops, roasts, ground meats, or meat food products that were cooked, cured, or smoked.

With the rise of catalog sales and use of the internet, today's retail venues may differ greatly from that traditional retail store. Consumers can now easily order meat food products, further prepared without FSIS inspection, under the retail store exemption, without leaving their homes.

The applicable regulatory requirements are found in 9 CFR 303.1(d)(1):

> (d)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.
>
> (2) For purposes of paragraph (d)(1) of this section:
>
> > (i) Operations of types traditionally and usually conducted at retail stores and restaurants are the following:
> >
> > > (a) Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts;
> > >
> > > (b) Grinding and freezing products made from meat;
> > >
> > > (c) Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;
> > >
> > > (d) Breaking bulk shipments of products;
> > >
> > > (e) Wrapping or rewrapping products.

Retail Store Criteria:

1. The retail exempt operation must have sales to consumers at the location where the meat food products are prepared under the exemption, as defined in 303.1(d)(1).
    a. Traditionally, this means a walk-in brick-and-mortar facility where a consumer can purchase meat from a retail display case.
    b. However, a retail store's sales can consist solely of orders placed by the consumer via fax, phone, or online, and shipped from the retail store, without actually having customers walk into the store.

2. In order to maintain eligibility for the retail store exemption sales can only be to consumers. There are two types of consumers:
    a. individual household consumers, and
    b. "other-than-household" consumers, more commonly known as hotels, restaurants and similar institutions (HRI) as determined by the Administrator in specific cases, as defined by 303.1(d)(2)(vi).

3. Neither slaughtering of livestock, nor retort processing (canning) of meat food products, can occur under the retail store exemption. Those activities require either Federal or State inspection in states that operate their own Meat and Poultry Inspection (MPI) programs (referred to as non-designated States).

4. A retail store can prepare multi-ingredient meat food products for sale to other-than-household consumers, within the limitations defined in 303.1(d)(2)(i)(c). Limitations on sales to other-than-household-consumers:
    a. If a retail exempt store prepared the meat food product by curing, cooking or smoking, rendering or refining the product, it cannot sell that product to other-than-household consumers, as defined in 303.1(d)(2)(iii)(f).
    b. A retail store could slice or grind meat that was cured, cooked or smoked under Federal or State inspection and sell that product to HRI accounts.
    c. Sales to HRI accounts cannot exceed 25% of total sales to consumers of retail-prepared meat. At least 75%, in terms of dollar value, of total sales of product represents sales of product to household consumers. This is known as the 75/25 Rule.
    d. Sales to HRI accounts cannot exceed the calendar year dollar limitation set by the Administrator.

5. For all sales, whether to individual household consumers or to HRI, no sale is made in excess of normal retail quantities, as defined in 9 CFR 303.1(d)(2)(ii).

    Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to be a normal retail quantity if the quantity so purchased does not in the aggregate exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified:

	One-half carcass pounds
Cattle	300
Calves	37.5
Sheep	27.5
Swine	100
Goats	25

6. Only federally inspected source materials can be used in the preparation of meat food products made for sales to consumers destined for interstate commerce. In states that operate their own MPI programs, State inspected source materials can be used in the preparation of meat food products that are limited to intrastate sales.

7. Records, such as bills of sale to consumers or cash register receipts, and raw ground beef production records (if applicable) are maintained as required by 9 CFR 320.1. FSIS OIEA Investigators are to have access to examine such records to verify compliance. The misbranding provisions of the FMIA apply to meat food products that are prepared under exemption from inspection requirements. Labeling of retail exempt meat food products is enforced by FSIS investigators, and by State or local authorities. State and local authorities use the FDA Food Code as guidance for labeling. Absent the following label features, per 9 CFR 301.2, *Misbranded*, a retail meat food product would be misbranded, if in a package or container, unless it bears a label showing:

    a. the name and place of business of the manufacturer, packer, or distributor;

b. an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

c. any word, statement, or other information (such as Safe Handling Instructions for meat products that are not RTE) required by or under authority of the Act;

d. the common or usual name of the food, if any there be;

e. the common or usual name of each ingredient if the product is fabricated from two or more ingredients;

f. a handling statement such as “Keep Refrigerated” or “Keep Frozen” if product requires special handling to maintain its wholesomeness;

g. nutrition labeling as specified in 9 CFR 317, Subpart B Nutrition Labeling, unless an exemption in 9 CFR 317.400 applies.

Retail Store Notes:

1. FSIS recommends that operations that are exempt from inspection are appropriately permitted through the State, local (county, city), and tribal authorities. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.

2. Typically, after permitting, the exempt operation will be subject to periodic inspections by the local authorities. Those inspections often compare the operations to the Food and Drug Administration’s Food Code.

3. To ensure the product does not become unwholesome or adulterated during mail order deliveries to consumers by a retail exempt operation, or its contracted couriers, the retailer and courier must safeguard against adulteration due to temperature abuse during transportation, per FMIA 21 U.S.C. 610(d), until the consumer takes possession of such product. USDA's Identifying Food Safety Risk Factors And Educational Strategies For Consumers Purchasing Seafood And Meat Products Online can be a valuable resource to retailers for making food safety determinations regarding mail order sales. Retailers and couriers need to be aware of the FDA’s Sanitary Transportation of Human and Animal Food requirements for shippers, loader and couriers.

4. The FMIA does not prohibit retail exempt store operators from using third-party businesses, such as a food hub, to:
    a. advertise,
    b. market,
    c. store product in commerce at an independent warehouse or food hub, prior to delivery to the consumer,
    d. deliver, and
    e. collect the money for the sale of their exempt products to consumers, but the retailer must sell the exempt meat or meat food product to the consumer in order to be exempt. The retailer cannot sell the product to the third-party business for re-sale to the consumer.

5. The FMIA does not prohibit a person, firm or corporation from preparing exempt meat food products at a central retail store location, for sale to consumers at that central location, and for unlimited distribution and subsequent sale to consumers at their satellite retail outlets, owned

or operated by them, such as their additional retail stores, kiosks, farmers market booths, or mobile food pantries.

6. FSIS recognizes that consumers may purchase raw meat or RTE meat products from a retail store via phone, fax, or online orders, and have that purchase delivered. Retailers that sell meat food products must maintain records, such as bills of sale, in accordance with 9 CFR 320, that disclose that sales were made to consumers at such location.

7. The total sales of product (303.1(d)(2)(iii)), and the annual dollar limitations for sales to other-than-household consumers, apply to individual retail stores, rather than cumulative retail stores operating under a corporate structure.

8. The sales of pass-through (box-in, box-out, not opened) meat food products that were federally inspected do not apply to the total sales of product found in 9 CFR 303.1(d)(2)(iii)(b). Those total sales limitations apply only to products prepared under the retail exemption. There is no limit on the sales of federal or state inspected products that are not further prepared at the retail establishment.

9. A retail store can donate meat food products that they prepared, or are selling, to non-profit organizations, but that product must have been from federally or state inspected source materials.

10. Meat food product prepared under the retail exemption will NOT bear the USDA marks of inspection on the label as it was prepared without inspection.

11. Labels applied at retail are not required to have FSIS sketch approval. A retailer may carry forward any special claims found on inspected source materials. A retailer cannot apply any new claim to the product prepared under the retail store exemption. It would be false and misleading (misbranding) to apply a claim which was not found on the source material. FSIS labeling guidance can be found in A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products.

D. RESTAURANTS

A restaurant is a business where meals, which may include meat food products, may be purchased. While a traditional restaurant experience may involve dining in, other restaurant business models include drive-thru windows, delivery, or carry-out options.

The applicable regulatory requirements are found in 9 CFR 303.1(d)(2)(iv).

Restaurant Criteria:

1. RTE meat food products are prepared for sale or service in meals or as entrees directly to individual consumers at such establishments.
2. Only federally or state inspected and passed product, or product prepared at a retail store exempted by 303.1(d)(2)(iii), is handled or used in the preparation of any product.

3. No sale of product is made in excess of a normal retail quantity as defined in 303.1(d)(2)(ii). See page 10.
4. The preparation of product is limited to traditional and usual operations as defined in 303.1(d)(2)(i). See page 8.
5. Records are maintained as required by 9 CFR 320.1.

Restaurant Notes:

1. The restaurant serves the individual consumers directly at the physical location where the RTE meat is prepared for immediate consumption.

2. Sales made by the restaurant are not subject to the 75/25 rule, nor the calendar year dollar limitation for retail stores, as restaurants do not sell exempt product to other-than-household consumers (HRI: hotels, restaurants and similar institutions).

3. The restaurant is subject to the State and local (county, city), and tribal inspection laws. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.

4. The restaurant is subject to the adulteration provisions of the FMIA per 9 CFR 303.1(f), therefore, the RTE meals must not be prepared, packed or held under insanitary conditions.

E. CATERERS

A caterer is a person who delivers or serves product in meals to individual consumers.

Caterer Criteria:

1. The definition of a restaurant includes a caterer, per 9 CFR 303.1(d)(2)(iv)(b). Product is prepared only for sale or service in meals or as entrees to individual consumers.
2. Only federally or state inspected and passed product, or such product prepared at a retail store exempted by 303.1(d)(1), is handled or used in the preparation of any product. Meals prepared from State-inspected source material are eligible solely for sale within such State.
3. No sale of product is made in excess of a normal retail quantity as defined in 303.1(d)(2)(ii) of this section.
4. The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.
5. Records are maintained as required by the FMIA 21 U.S.C. 642 and 9 CFR 320.1, which include records that fully and correctly disclose all transactions involved in their business.

Caterer Notes:

1. The caterer is a subset of the restaurant exemption. Caterers must meet the terms of the restaurant exemption, delineated above in 1-5, in order to be eligible for the exemption from Federal inspection.

2. The caterer, or their employees delivers or serves the meals, or entrées, to the individual consumers, per 9 CFR 303.1(d)(2)(iv)(b).

3. In order to maintain eligibility for the catering exemption sales can only be to individual consumers. Products not sold to consumers disqualify the caterer from the exemption and the caterer must apply for a grant of inspection. Records which fully and correctly disclose the sale of the catered product to the consumer are required per 9 CFR 320.1(b)(1).

4. The caterer is subject to in-commerce surveillance reviews by FSIS OIEA investigators, including access and examination of facilities, inventory, and records, per FMIA 21 U.S.C. 642 The caterer is also subject to State and local licensing requirements and periodic inspection by local authorities to ensure proper sanitation and food handling.

5. The caterer is subject to the adulteration provisions of the FMIA per 9 CFR 303.1(f), therefore, the catered RTE meals must not be prepared, packed or held under insanitary conditions. The caterer, or their employees, should consider storage, holding, and reheating conditions in order to ensure delivery to consumers of a safe, unadulterated meal. Inadequate storage, holding, or reheating temperatures could lead to dangerous levels of pathogens in the foods.

F. RESTAURANT CENTRAL KITCHENS

The increase in large restaurant chains and fast food operations has contributed to a trend in the centralization of meat preparation systems. By centralizing preparation of products, a restaurant business can improve its efficiency. A restaurant central kitchen (RCK) exemption is provided, in 9 CFR 303.1(d)(2)(iv))(c), for a central kitchen that prepares RTE meat products for sale to consumers at their satellite restaurants.

Restaurant Central Kitchen Criteria:

1. The product is RTE upon departure from the RCK (i.e., no further preparation such as cooking is needed, except that it may be reheated prior to serving).
2. The transportation is direct between the RCK and satellite restaurant or vending machine location with no intervening transfer or storage. Only federally inspected source materials can be used in the preparation of meat food products destined for interstate sales. Meals prepared from State-inspected source material are eligible solely for sale within such State.
3. The product is to be served, without intervening sale, in meals or as entrées only to customers at satellite restaurants, or through vending machines, owned or operated by the same individual, firm, or corporation owning or operating the restaurant central kitchen.
4. The facilities are maintained in a sanitary manner.
5. Records are maintained as required by 9 CFR 320.1.

Restaurant Central Kitchen Notes:

1. The RCK may or may not serve consumers at the RCK location.
2. The RCK is subject to the State and local (county, city) inspection laws. Check with those authorities for their applicable licensing requirements and applicable foodservice ordinances.
3. All RCKs are subject to periodic inspection by local governments and by FSIS to ensure proper sanitation and food handling.

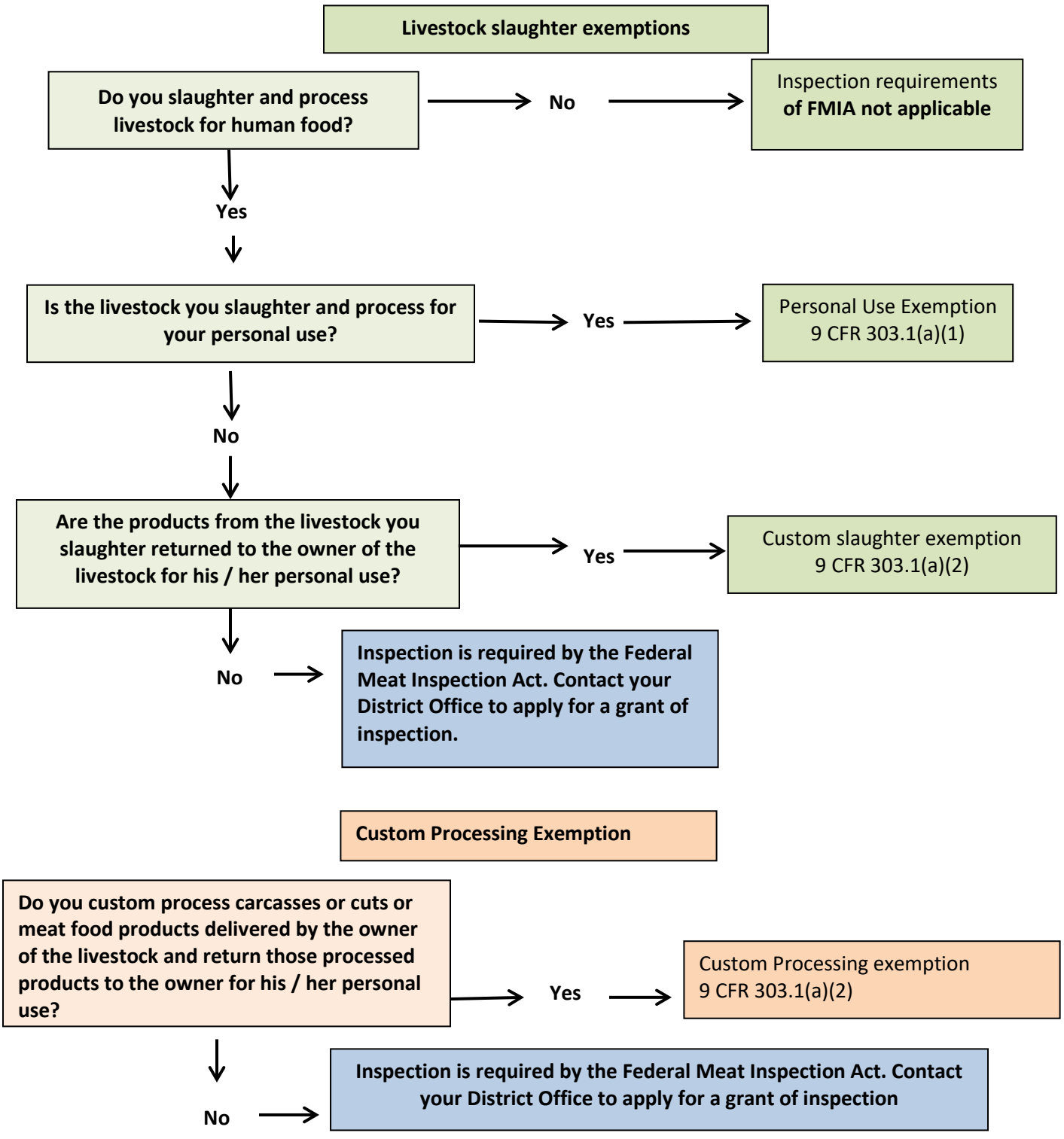
4. To lessen the likelihood of product mishandling and potential adulteration, the RTE product must be sent directly to the satellite restaurant by satellite restaurant or RCK employees. Distribution to franchise restaurants is acceptable if the franchises are owned or operated by the same person, firm or corporation that owns or operates the RCK.

5. If refrigerated prior to delivery, good manufacturing practices should be used that ensure the RTE meals are kept at 40°F or below.

6. RCKs operated by a city, county, or State also qualify for the exemption, provided meals are served at facilities controlled by the city, county, or State.

How do I determine if I am eligible for one of these exemptions?

In order to determine whether your livestock slaughter or meat processing operation qualifies for an exemption from the Federal Meat Inspection Act, ask yourself the question in the bold type and then follow the appropriate Yes or No response arrow.



In order to determine whether your retail, restaurant, central kitchen or catering operation qualifies for an exemption from the Federal Meat Inspection Act, ask yourself the question in the bold type and then follow the appropriate response arrow.

Do you purchase and prepare inspected livestock carcasses and / or inspected meat or meat products and sell products to consumers at your retail store(s) or outlet(s)? → Yes → **Retail exemption:** sales to household consumers only 9 CFR 303.1(d)(2)(iii)(a)

Do you purchase meat or meat products[1] and prepare the products as ready to eat entrees for meals sold directly to consumers? → Yes → **Restaurant exemption** 9 CFR 303.1(d)(2)(iv)

Do you purchase meat or meat products[1], prepare these products, and then sell them in meals as a catering business? → Yes → **Catering Exemption** 9CFR 303.1(d)(2)(iv)(b)

Do you purchase meat or meat products[1] and prepare them in a central kitchen for distribution as ready to eat meals or vending machines which you own / operate? → Yes → **Central kitchen Exemption** 9 CFR 303.1(d)(2)(iv)(c)

Do you purchase meat products, further process these products and then wholesale these products? → Yes → **Inspection is required by the Federal Meat Inspection Act. Contact your District Office to apply for a grant of inspection.**

[1] Must start with inspected and passed product or raw product prepared at a retail exempt store

Considerations for Meat Sold in Local and Regional Markets

Growing consumer demand for local food is creating new challenges and opportunities for producers. Farmers and ranchers selling into local and regional food systems have unique needs - from navigating seeds, breeds, and production systems to adopting on-farm risk management and food safety activities. USDA supports and invests in local and regional food systems from coast to coast, in every state, as part of the department's commitment to revitalizing rural America. USDA strengthens local and regional food systems by coordinating relevant activities across its 17 agencies and by investing in projects that recruit and train farmers and ranchers, expand economic opportunities for small businesses, and increase access to healthy foods. Consumers across the country can find locally produced food at their neighborhood grocery stores, restaurants, and farmers markets. Learn more about USDA's tools and programs to help farmers, ranchers, processors, and distributors produce food for local and regional markets at USDA Agricultural Marketing Service, Local and Regional Food Sector.

The information below provides guidance for meat production in a variety of local market business models.

Local Marketing and Direct-to-Consumer sales

Consumers and businesses are increasingly interested in direct, regional, and local markets that minimize the distance that food products travel from production to consumption. Local and regional sales can be either direct-to-consumer – for example, through farmers markets or Community Supported Agriculture – or sold through so-called "intermediated markets" such as food hubs, which then market to consumers.

Local and regional marketing can add value to a food product by maintaining farm identity in marketing, building relationships and loyalty between consumers and producers, targeting specialty or niche markets, and making production practices and ingredients more transparent. USDA does not officially define local or regional, so the exact meaning of the terms currently used in commerce may vary depending on the goals of the producer, buyer, or organization promoting local market connections.

Local and Regional Marketing and Direct-to-Consumer Sales Notes:

- When selling locally-produced meat direct to consumers, keep in mind that only livestock slaughtered and processed under Federal inspection can be sold across state lines (interstate). Meat from livestock slaughtered and processed under State inspection is limited to commerce within the state (intrastate).
- If slaughtered and processed under Federal or State inspection, local meat can be sold direct to household consumers through farmers markets and to other-than-household consumers, within limitations described above in Retail Store Criteria, page 8.
- If local meat products are slaughtered under Federal or State inspection and are then further prepared (i.e. operations of types traditionally and usually conducted at retail stores: see 9 CFR 303.1(d)(2)), by a local seller, the local seller must be inspected unless it is eligible for the retail store exemption (see page 8). Retail stores that are exempt from Federal inspection, however, are subject to State and local (city, county) inspection laws.

For all local and regional food markets, FSIS recommends:

- Farmers and businesses follow voluntary food safety practices to ensure a standard of care for their products and to reassure buyers regarding the steps taken to reduce risks of foodborne illness.
- Farmers and businesses reduce the risk of dangerous bacteria or toxins in farm products by following established food safety guidance, including the following:
    - develop a food safety plan,
    - train employees in proper food safety management, and
    - document all farm practices.

Emerging Local and Regional Food Business Models

What are some of the emerging business models?

Business models, including those described below, are emerging as a result of the growing demand for locally and regionally produced food.

Farmers Markets

A farmers market is an open retail market that features fruits, vegetables, meats, eggs, and other commodities sold directly from producer to consumers. Typically, each producer brings their own booth, tables, or stands, and consumers purchases products directly from the farmers. This facilitates personal connections and creates mutual benefits for local producers, consumers, and communities. USDA's Agricultural Marketing Service (AMS) defines a farmers market as markets that feature two or more farm vendors selling agricultural products directly to customers at a common, recurrent physical location.

Farmers Markets Notes:

1. Livestock meat food products, like beef jerky, must have been prepared from federally or state inspected source material. If the meat food product sold at the farmers market is moved in interstate commerce, then the source material used to prepare the meat food product must be federally inspected.
2. FSIS OIEA Compliance Investigators may do reviews of booths selling meat food products, in accordance with FSIS Directive 8010.1.
3. Typically, the booths are appropriately permitted by the local (county, city) authorities and regulated by the local food establishment requirements.
4. Onsite preparation of meat food products at farmers markets may be regulated by State and local laws, or the farmers market's own food safety rules.
5. A farmers market booth can be an additional retail outlet of a retail store, where product is sold to individual household consumers in normal retail quantities.
6. Perishable meat should be properly refrigerated at the market and be kept in closed coolers with adequate amounts of ice to maintain cool temperatures. See FSIS Refrigeration and Food Safety guidance for more information.

7. Raw meat should be handled appropriately so that the juices, which may contain harmful bacteria, do not come in contact with other foods or food contact surfaces.
8. RTE meat products should not be handled with bare hands, or by ill food handlers.
9. Packaged meat food products must not be misbranded. Be sure the label contains:
    a. The common name of the meat food product.
    b. A list of ingredients if there are more than two ingredients, in descending order of predominance.
    c. Net quantity specifications (weight, volume).
    d. Name and address of the business that prepared the meat food product.
    e. No marks of USDA inspection, or state inspection, unless the meat food product was actually prepared under inspection and is still intact as prepared and packaged by the federally or state inspected establishment.
    h. Safe-handling instructions if the product is raw.
    i. A handling statement such as “Keep Refrigerated” or “Keep Frozen” if product requires special handling to maintain its wholesomeness.
    f. nutrition labeling as specified in 9 CFR 317, Subpart B Nutrition Labeling, unless an exemption in 9 CFR 317.400 applies.
10. Check with your State and local (county, city) authorities about using a private kitchen in a person’s living quarters for preparing meat food products sold at farmers markets.

Food Hubs

A food hub is a business or organization that actively manages the aggregation, distribution, and marketing of source-identified food products – primarily from local and regional producers – to strengthen their ability to satisfy wholesale, retail, and institutional demand. They provide a bridge from food producer to consumer by creating a business that actively works to distribute and market locally and regionally sourced food products. By providing small producers with access to larger volume markets, food hubs can support producers while also helping buyers meet the growing consumer demand for local food.

Food Hub Notes:

1. Food hubs can advertise, broker, and deliver retail exempt meat food products for the exempt operator, but the exempt operator must maintain ownership of the product and make the sale to the consumer in order to be exempt from inspection. The records maintained by the retailer must fully and correctly disclose the sale of the meat food product from the retailer to the consumer.
2. The food hub may market:
    - federally inspected product in intact packages from the federally inspected establishment, which is eligible to move in interstate commerce,
    - State inspected product in intact packages from the state inspected establishment, which is eligible to move only in intrastate commerce,

- Retail exempt product prepared under the retail store exemption, which is owned by the retailer. The retail exempt operator must own and sell the retail exempt product to the consumer. Bills of sale, which fully and correctly disclose the sale of the exempt product by the retail exempt operator to the consumer, must be maintained.
    - Retail exempt product prepared from Federally inspected source materials product may move in interstate commerce.
    - Retail exempt product prepared from state inspected source material, in those States that operate their own meat and poultry inspection (MPI) programs, are restricted to intrastate commerce only.

3. The food hub must maintain records, per 9 CFR 320.1, such as invoices, bills of lading, and receiving and shipping papers for any meat food product that is shipped, received, transported or otherwise handled. All such records are subject to examination by USDA Investigators.
4. The food hub must register with the USDA as a meat food handler (transporting in commerce) with FSIS Form 5020-1, Registration of Meat and Poultry Handlers.
5. Generally speaking, food hubs do not prepare meat food products. If a food hub prepares (see: 9 CFR 301.2 definition for *prepared*) meat food products, then it must do so under inspection, or under one of the exemptions described above.

Farm to School

Within local and regional markets, schools offer a compelling opportunity to connect young people to local food and agriculture. Farm to school initiatives include efforts to bring locally or regionally produced foods into school cafeterias; hands-on learning activities such as school gardening, farm visits, and culinary classes; and the integration of food-related education into the regular, standards-based classroom curriculum. Locally sourced food (which creates economic opportunities for local food producers) can span the school meal tray and include everything from fresh fruit and vegetable servings to the wheat in the pizza crust, beans in the chili, rice in the stir fry, turkey in the sandwiches, and cheese in the quesadillas. Farm to school includes all types of producers and food businesses, including farmers, ranchers, and fishermen, as well as food processors, manufacturers, and distributors.

Farm to School Notes:

FSIS requirements:

1. All meat products that are to be served in a school lunch program must be, at a minimum, slaughtered in a federally or state inspected facility.
2. Meat and meat food products may be further prepared under the exemptions described above only if sold to consumers. Consumers are defined in 9 CFR 303.1(d)(2)(vi). Schools are an other-than-household consumer as an institution similar to a hotel.
3. Animals that are slaughtered or processed under a custom exemption, or under the personal use exemption, are not allowed to be used in school lunch programs. That meat is to be used exclusively by the owner of the animal in their household.

Additionally, FSIS recommends that farmers and schools involved in farm to school or school garden programs follow accepted food safety practices and have a food safety plan in place to reduce the risk of foodborne illnesses. More guidance for schools interested in procuring local meat, poultry,

game, and eggs for child nutrition programs is available here: http://www.fns.usda.gov/procuring-local-meat-poultry-game-and-eggs-child-nutrition-programs .

Online Markets

Online markets are much like food hubs in that they bridge the gap from food producer to consumer, but instead of having a physical market, all transactions are performed through the Internet. This gives consumers the convenience of placing orders online with established producers who sell fresh, local goods. Often, an online market will feature products from many different producers.

In some cases, the online marketplace does not take ownership of the product, but simply provides services such as:

- advertising/marketing,
- hosting the platform on which the products are marketed to consumers,
- transporting or distributing the product,
- collecting the money for the sale of the products to consumers.

The FMIA does not prohibit a person, firm or corporation from performing these online marketing services for a retail exempt operator. The FSIS policy is, therefore, that an online market (or a food hub) is not precluded from acting as an agent of the retailer. The online market and the retail exempt operator would be expected to provide documentary proof of their agency relationship. Both the retail exempt operator and the online market would be required to keep records and to fully and correctly disclose all transactions involved in their business, per 9 CFR 320.1, including bills of sale from the retail exempt operator to the consumer for the meat food product produced under exemption and sold to the consumer.

Online Market Notes:

1. Retail exempt meat food products offered on an online market must be owned by the retailer, not by the online market.
2. In order to be exempt, the retail store must sell the product to the consumer.
3. The online market must register with the USDA as a meat food handler (broker or transporter) with FSIS Form 5020-1.

Home Delivered Meals

Home delivered meals programs deliver prepared meals or meal kits for in-home preparation to consumers. Many new companies are following this idea and creating businesses that design and deliver fresh, healthy meals to consumer's doorsteps. These companies may market their products as a way to lose weight or conveniently follow a healthier lifestyle by including fresh, locally sourced products in their meals.

Home Delivered Meals Notes:

1. Since they sell either RTE or uncooked meals to consumers, they are a retail store. As such, see the retail store exemption criteria and notes above starting on page 8.

2. The Home Delivered Meals business is subject to the state and local (county, city) inspection laws. Check with those authorities for their applicable licensing requirements and applicable food establishment ordinances.

How does FSIS verify that facilities exempt from inspection meet applicable requirements?

States with "equal to" meat inspection programs, or FSIS's Office of Field Operations (OFO) District Office, or FSIS OIEA designated personnel typically review custom exempt operations.

At retail stores, warehouses, and other in-commerce establishments, OIEA Compliance Investigators conduct onsite reviews to verify compliance with the FMIA and FSIS's regulations. The investigators, or any duly authorized representative of the Secretary, also have access to your place of business at all reasonable times and have the opportunity to examine your facility, inventory, and records.

Although your business may not be subject to the daily inspection requirements by the FSIS, FSIS still has statutory authority, per FMIA 21 U.S.C. 672, to detain (to officially prevent the meat food product from leaving a place) your exempt product should it be found to be adulterated or misbranded.

At facilities that house both an official establishment and a retail exempt establishment, the OFO inspectors will verify that sanitary conditions are maintained for the federally inspected establishment. The State and local government, or the FSIS OIEA Compliance Investigators, will verify the exempt operations meets sanitation and recordkeeping requirements. If your facility houses both an official establishment and an exempt establishment, be aware you will have to maintain separation between the official (inspected) and unofficial (exempt) establishments per 9 CFR 305.2(a), and, as always, maintain sanitary conditions for both operations. If OFO inspectors have concerns about the exempt facility, they will not inspect that operation, but they will turn over their concerns to the OIEA Compliance Investigators.

What other government entity will have an active role in my exempt business

While FSIS maintains jurisdiction over amenable meat food products that are "in-commerce," the Department of Health and Human Service Food and Drug Administration (FDA) regulates all food service establishments and food processing establishments that are not under FSIS jurisdiction. FDA regulates food products not under FSIS inspection such as rabbit, buffalo, venison (if none of these are under FSIS voluntary inspection), fish (except of the order Siluriformes), seafood, and food ingredients introduced into or offered for sale in interstate commerce. The FDA's regulations are in Title 21 of the CFR.

The FDA also provides a uniform Food Code that many States and local authorities have adopted to safeguard public health and ensure that food is unadulterated and honestly presented when offered to consumers.

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that food facilities register with FDA. Be aware of any impact the FDA's rules under the Food Safety and Modernization Act has on your exempt business or related business.

Generally, the FDA does not inspect retail food service establishments. The retail food establishments are regulated by State and local (county, city) governments, although FDA retains jurisdiction over these retail operations. More than 3,000 State, local, and tribal agencies have primary responsibility to regulate the retail food and foodservice industries in the United States. They are responsible for the inspection and oversight of over 1 million food establishments – restaurants

and grocery stores, as well as vending machines, cafeterias, and other outlets in health-care facilities, schools, and correctional facilities. Most custom exempt operations are under State or local regulation as well.

You can use the Directory of State and Local Officials to obtain more information from State and local regulatory officials involved with food and food defense.

The slaughter of other animals for food is regulated by the Food and Drug Administration (FDA). However, FSIS provides voluntary inspection on a fee-for-service basis for certain species, including bison, buffalo, deer, rabbits, migratory water fowl, and game birds (see 9 CFR 352, 354, and 362). Some States do consider these species to be inspected under State inspection.

What is meant by "in commerce" with regards to exempted meat food products?

For the purpose of this regulation, the Agency defines "in commerce" as product that is out of the producing establishment's direct control and is in distribution (e.g., in another Federal establishment, in a warehouse, distribution center, retail facility, restaurant, or other institution). Domestic product is considered in commerce if it has been shipped from a firm without Agency or firm controls or restrictions and is free to be moved to any consignee or to consumers.

The term "of commerce" (9 CFR 302.1(a)(1), or "for commerce" (9 CFR 320.1(a)(1)) means an article of human food being offered for commercial gain.

Custom exempt meat food products may be transported "in commerce" from the location where the animal was slaughtered or processed to the owner of the animal from which the meat was derived. The custom exempt meat food products must not bear the mark of inspection, since they were not prepared under USDA inspection, and must be marked Not for Sale.

Meat food products prepared under the retail store or restaurant exemptions from federally inspected meat sources may move in interstate commerce. Therefore, products sold to consumers in other states (including products shipped to consumers in other states) must be derived from USDA inspected source materials. Retail-exempt meat food products prepared from state inspected product can be sold solely within such State.

Additional Guidance

- Sanitation Guidance for Beef Grinders
- Best Practices Guidance for Controlling ***Listeria monocytogenes*** (Lm) in Retail Delicatessens
- FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments
- Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act
- Sanitation Performance Standards Compliance Guide
- USDA National Agricultural Library, Food Safety Information Center
- MOBILE SLAUGHTER UNIT COMPLIANCE GUIDE
- USDA's Farm to School Program
- Local Meat in Schools Fact Sheet
- USDA FNS Procuring Local Meat, Poultry, Game, and Eggs for Child Nutrition Programs
- FDA Food Safety Modernization Act
- Sanitary Transportation of Human and Animal Food
- Requirements for the Disposition of Cattle that Become Non-Ambulatory Disabled Following Ante-Mortem Inspection
- FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork and Products Containing Pork
- AFDO Retail Meat and Poultry Processing Guidelines
- Using Dentition to Age Cattle

Attachment 1: A Summary Table of Exemptions and Limitations

Criteria	Personal Use Exemption	Custom Slaughter Exemption	Custom Processing Exemption	Retail Store Exemption	Restaurant Exemption	Restaurant Central Kitchen Exemption	Catering Exemption
Do I need to own the animal?	Yes	Yes, client must own the livestock	Yes, client must own the livestock	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Required to start with Inspected and Passed product?	No	No	No	Yes	Yes, or certain products prepared at a retail exempt store	Yes, or certain products prepared at a retail exempt store	Yes, or certain products prepared at a retail exempt store
Donate to nonprofit organization?	No	No	No	Yes	Yes	Yes	Yes
Retort Processing (canning) allowed?	Yes	Not Applicable	Yes	No	No	No	No
				Yes - Individual			
Sales allowed in normal retail quantities?	Cannot be sold or donated	Cannot be sold or donated	Cannot be sold or donated	Yes, sales to HRI cannot exceed 25% of total sales. Sales to HRI cannot exceed yearly dollar limitations	Yes, cannot be made in excess of normal retail quantity	Yes, cannot be made in excess of normal retail quantity	Yes, cannot be made in excess of normal retail quantities
							Yes

Attachment 2: Definitions

1 THE FOLLOWING REGULATORY AND COMMON STANDARD DICTIONARY DEFINITIONS WILL BE USEFUL IN UNDERSTANDING THE EXEMPTIONS.

Regulatory definitions (found in 9 CFR 300-599):

Exotic animal. Any reindeer, elk, deer, antelope, water buffalo, yak or bison

Firm. Any partnership, association, or other unincorporated business organization.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

"Inspected and passed" or "U.S. Inspected and Passed" or "U.S. Inspected and Passed by Department of Agriculture" (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Livestock. Cattle, sheep, swine, or goat.

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

Misbranded. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (vv)(7)(ii) of this section unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Official establishment. Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article or animal under the Act.

Person. Any individual, firm, or corporation.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

Restaurant. A food establishment where product is prepared for sale or service as RTE meals to individual consumers at such establishments.

Retort. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

Voluntary inspection service. An inspection and certification service for wholesomeness relating to the slaughter and processing of exotic animals and the processing of exotic animal products.

Regulatory definitions (found in FDA Food Code 2017)

CFR. Code of Federal Regulations

Comminuted. Reduced in size by methods including chopping, flaking, grinding, or mincing.

Consumer. A person who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale.

Employee. The PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

FDA. The U.S. Food and Drug Administration.

Food employee. An individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.

Food Establishment.

(1) "Food establishment" means an operation that:

(a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and

(b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(2) "Food establishment" includes: (a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the REGULATORY AUTHORITY; and

(b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

(3) "Food establishment" does not include: (a) An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;

(b) A produce stand that only offers whole, uncut fresh fruits and vegetables;

(c) A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT

(d) A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;

(e) An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;

(f) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; or

(g) A private home that receives catered or home-delivered FOOD.

Game Animal.

(1) "Game animal" means an animal, the products of which are FOOD, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as Poultry.

(2) "Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

(3) "Game animal" does not include RATITES.

HACCP plan. Means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Law. Means applicable local, state, and federal statutes, regulations, and ordinances.

Permit. Means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

Premises. Means:

(1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or

(2) The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

Regulatory authority. Means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

Vending machine. Means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

Terms with no regulatory definition

(If neither 9 Code of Federal Regulations (CFR), nor 21 CFR, nor the Statute defines a term, then the usage found in any **Standard American English dictionary** applies.)

Broker: a person who helps other people to reach agreements, to make deals, or to buy and sell property (such as stocks or houses)

1.1.1.1 Community Supported Agriculture (CSA): *a system in which a farm operation is supported by shareholders within the community who share both the benefits and risks of food production.*

Courier: a person who transports a meat food product to the consumer

Mail order: a meat food product that is sent by mail to the consumer who bought it

Operate: control the functioning of (a machine, process, or system).

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Title 9
Animals and Animal Products

Part 200 to End

Revised as of January 1, 2019

Containing a codification of documents
of general applicability and future effect

As of January 1, 2019

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To cite the regulations in this volume use title, part and section number. Thus, 9 CFR 201.1 *refers to title 9, part 201, section 1.*

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Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
Title 28 through Title 41.....as of July 1
Title 42 through Title 50.....as of October 1

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An index to the text of ''Title 3—The President'' is carried within that volume.

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OLIVER A. POTTS,
Director,
Office of the Federal Register
January 1, 2019

THIS TITLE

Title 9—ANIMALS AND ANIMAL PRODUCTS is composed of two volumes. The first volume contains chapter I—Animal and Plant Health Inspection Service, Department of Agriculture (parts 1–199). The second volume contains chapter II—Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs), Department of Agriculture and chapter III—Food Safety and Inspection Service, Department of Agriculture (part 200–end). The contents of these volumes represent all current regulations codified under this title of the CFR as of January 1, 2019.

For this volume, Stephen J. Frattini was Chief Editor. The Code of Federal Regulations publication program is under the direction of John Hyrum Martinez.

Title 9—Animals and Animal Products

(This book contains part 200 to end)

EDITORIAL NOTE: Other regulations issued by the Department of Agriculture appear in title 7, title 36, chapter II, and title 41, chapter 4.

CHAPTER II—GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION (PACKERS AND STOCKYARDS PROGRAMS), DEPARTMENT OF AGRICULTURE

PART 200 [RESERVED]

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AUTHORITY: 7 U.S.C. 181–229c.

DEFINITIONS

§ 201.1 Meaning of words.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

[19 FR 4524, July 22, 1954]

§ 201.2 Terms defined.

The definitions of terms contained in the Act shall apply to such terms when used in the Regulations under the Packers and Stockyards Act, 9 CFR part 201; Rules of Practice Governing Proceedings under the Packers and Stockyards Act, 9 CFR part 202; Statements of General Policy under the Packers and Stockyards Act, 9 CFR part 203; and Organization and Functions, 9 CFR part 204. In addition the following terms used in these parts shall be construed to mean:

(a) *Act* means the Packers and Stockyards Act, 1921, as amended and supplemented (7 U.S.C. 181 *et seq.*).

(b) *Department* means the United States Department of Agriculture.

(c) *Secretary* means the Secretary of Agriculture of the United States, or any officer or employee of the Department authorized to act for the Secretary.

(d) *Administration* or *agency* means the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs).

(e) *Administrator* or *agency head* means the Administrator of the Administration or any person authorized to act for the Administrator.

(f) *Regional Supervisor* means the regional supervisor of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) for a given area or any person authorized to act for the regional supervisor.

(g) *Person* means individuals, partnerships, corporations, and associations.

(h) *Registrant* means any person registered pursuant to the provisions of the Act and the regulations in this part.

(i) *Stockyard* means a livestock market which has received notice under section 302(b) of the Act that it has been determined by the Secretary to come within the definition of ''stockyard'' under section 302(a) of the Act.

(j) *Schedule* means a tariff of rates and charges filed by stockyard owners and market agencies.

(k) *Custom Feedlot* means any facility which is used in its entirety or in part for the purpose of feeding livestock for the accounts of others, but does not include feeding incidental to the sale or transportation of livestock.

(l) [Reserved]

(m) *Principal part of performance* means the raising of, and caring for livestock or poultry, when used in connection with a livestock or poultry production contract.

(n) *Additional capital investment* means a combined amount of $12,500 or more per structure paid by a poultry grower or swine production contract grower over the life of the poultry growing arrangement or swine production contract beyond the initial investment for facilities used to grow, raise and care for poultry or swine. Such term includes the total cost of upgrades to the structure, upgrades of equipment located in and around each structure, goods and professional services that are directly attributable to the additional capital investment. The term does not include costs of maintenance or repair.

[46 FR 50510, Oct. 14, 1981, as amended at 76 FR 76888, Dec. 9, 2011; 80 FR 6430, Feb. 5, 2015]

ADMINISTRATION

§ 201.3 Applicability of regulations in this part.

The regulations in this part, when governing or affecting contracts, shall

apply to any poultry growing arrangement, swine production contract, or any other livestock or poultry contract entered into, amended, altered, modified, renewed or extended after February 7, 2012.

[76 FR 76889, Dec. 9, 2011, as amended at 80 FR 6430, Feb. 5, 2015]

§ 201.4 Authority.

The Administrator shall perform such duties as the Secretary may require in enforcing the provisions of the act and the regulations in this part.

[19 FR 4524, July 22, 1954. Redesignated at 76 FR 76889, Dec. 9, 2011]

APPLICABILITY OF INDUSTRY RULES

§ 201.5 Bylaws, rules and regulations, and requirements of exchanges, associations, or other organizations; applicability, establishment.

(a) The regulations in this part shall not prevent the legitimate application or enforcement of any valid bylaw, rule or regulation, or requirement of any exchange, association, or other organization, or any other valid law, rule or regulation, or requirement to which any packer, stockyard owner, market agency, or dealer shall be subject which is not inconsistent or in conflict with the act and the regulations in this part.

(b) Market agencies selling livestock on commission shall not, in carrying out the statutory duty imposed upon them by section 307 of title III of the act, permit dealers, packers, or others representing interests which conflict with those of consignors, to participate, directly or indirectly, in determination of the need for, or in the establishment of, regulations governing, or practices relating to, the responsibilities, duties, or obligations of such market agencies to their consignors.

(7 U.S.C. 181 *et seq.*)

[19 FR 4524, July 22, 1954, as amended at 44 FR 45361, Aug. 2, 1979. Redesignated at 76 FR 76889, Dec. 9, 2011]

REGISTRATION

§ 201.10 Requirements and procedures.

(a) Every person operating or desiring to operate as a market agency or dealer as defined in section 301 of the Act (7 U.S.C. 201) must apply for registration. To apply, such persons must file a properly executed application for registration on a form furnished by the Agency. Each applicant must file an application for registration with the regional office for the region where the applicant has his or her primary place of business, and file and maintain a bond as required in §§ 201.27 through 201.34 (9 CFR 201.27 through 201.34).

(b) If, upon review of an application, the Administrator has reason to believe the applicant is unfit to engage in the activity for which application has been made, a proceeding shall be instituted promptly affording the applicant the opportunity for a full hearing, in accordance with the Department's Rule of Practice Governing Formal Adjudicatory Proceedings (7 CFR Subpart H), to show cause why the application for registration should not be denied. If after the hearing the application is denied, as soon as the issue(s) that formed the basis of the denial have been remedied, the applicant may file a new application for registration.

(c) Any person regularly employed on salary, or other comparable method of compensation, by a packer to buy livestock for such packer is subject to the regulation requirements of this section. Such person must be registered as a dealer to purchase livestock for slaughter on behalf of the packer.

(d) Every person clearing or desiring to clear the buying operations of other registrants must apply for registration as a market agency providing clearing services by filing a properly executed application on a form furnished by the Agency, and file and maintain a bond as required in §§ 201.27 through 201.34.

(e) If an application for registration is granted, a market agency or dealer receives an acceptance letter from the Agency that issues the registration number and the effective date of the registration. Each registration issued in accordance with this section will not expire, provided that the registrant timely files its annual report with the Agency as required in section 201.97. Failure of a registrant to file an annual report by the date required in section 201.97 will result in the issuance of a

default notice. Thirty days after receipt of the default notice, the registration will expire if the Agency does not receive an annual report from the registrant. A registrant who fails to renew its registration in a timely manner, and continues to operate, will be engaged in business subject to the Act without a valid registration in violation of section 303 of the Act (7 U.S.C. 203).

(f) Registrations that expire during a period of suspension imposed as a result of an order or injunction may be renewed, but the renewal will not be effective until the specified suspension period terminates.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 203, 204, 207, 217a, 222 and 228)

[49 FR 33003, Aug. 20, 1984, as amended at 54 FR 37094, Sept. 7, 1989; 56 FR 2127, Jan. 22, 1991; 68 FR 75388, Dec. 31, 2003; 75 FR 6300, Feb. 9, 2010]

§ 201.11 Suspended registrants; officers, agents, and employees.

Any person whose registration has been suspended, or any person who was responsible for or participated in the violation on which the order of suspension was based, may not register in his own name or in any other manner within the period during which the order of suspension is in effect, and no partnership or corporation in which any such person has a substantial financial interest or exercises management responsibility or control may be registered during such period.

(7 U.S.C. 203, 204, 207, 217a and 228)

[49 FR 33003, Aug. 20, 1984]

SCHEDULES OF RATES AND CHARGES

§ 201.17 Requirements for filing tariffs.

(a) *Schedules of rate changes for stockyard services.* Each stockyard owner and market agency operating at a posted stockyard shall file with the regional supervisor for the region in which they operate a signed copy of all schedules of rates and charges, supplements and amendments thereto. The schedules, supplements and amendments must be conspicuously posted for public inspection at the stockyard, and filed with the regional supervisor, at least 10 days before their effective dates, except as provided in paragraphs (b) and (c) of this section. Each schedule, supplement and amendment shall set forth its effective date, a description of the stockyard services rendered, the stockyard at which it applies, the name and address of the stockyard owner or market agency, the kind of livestock covered by it, and any rules or regulations which affect any rate or charge contained therein. Each schedule of rates and charges filed shall be designated by successive numbers. Each supplement and amendment to such schedule shall be numbered and shall designate the number of the schedule which it supplements or amends.

(b) *Feed charges.* When the schedule in effect provides for feed charges to be based on an average cost plus a specified margin, the 10-day filing and notice provision contained in section 306(c) of the Act is waived. A schedule of the current feed charges based on average feed cost and showing the effective date shall be conspicuously posted at the stockyard at all times. Changes in feed charges may become effective 2 days after the change is posted at the stockyard.

(c) *Professional veterinary services.* The 10-day filing and notice provision contained in section 306(a) of the Act is waived for a schedule of charges for professional veterinary services. A schedule of charges for professional veterinary services rendered by a veterinarian at a posted stockyard shall be conspicuously posted at the stockyard at all times. The schedule of charges and any supplement or amendment thereto may become effective 2 days after the schedule, supplement, or amendment is posted at the stockyard.

(d) *Joint schedules.* If the same schedule is to be observed by more than one market agency operating at any one stockyard, one schedule will suffice for such market agencies. The names and business addresses of those market

agencies adhering to such schedule must appear on the schedule.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 203, 204, 207, 217a, 222 and 228)

[49 FR 33003, Aug. 20, 1984, as amended at 68 FR 75388, Dec. 31, 2003]

GENERAL BONDING PROVISIONS

§ 201.27 Underwriter; equivalent in lieu of bonds; standard forms.

(a) The surety on bonds maintained under the regulations in this part shall be a surety company which is currently approved by the United States Treasury Department for bonds executed to the United States; and which has not failed or refused to satisfy its legal obligations under bonds issued under said regulations.

(b) Any packer, market agency, or dealer required to maintain a surety bond under these regulations may elect to maintain, in whole or partial substitution for such surety bond, a bond equivalent as provided below. The total amount of any such surety bond, equivalent, or combination thereof, must be the total amount of the surety bond otherwise required under these regulations. Any such bond equivalent must be in the form of:

(1) A trust fund agreement governing funds actually deposited or invested in fully negotiable obligations of the United States or Federally-insured deposits or accounts in the name of and readily convertible to currency by a trustee as provided in § 201.32, or

(2) A trust agreement governing funds which may be drawn by a trustee as provided in § 201.32, under one or more irrevocable, transferrable, standby letters of credit, issued by a Federally-insured bank or institution and physically received and retained by such trustee.

(c) The provisions of §§ 201.27 through 201.34 shall be applicable to the trust fund agreements, trust agreements and letters of credit authorized in paragraph (b) of this section.

(d) Bonds, trust fund agreements, letters of credit and trust agreements shall be filed on forms approved by the Administrator.

(Approved by the Office of Management and Budget under control number 0580–0015)

[56 FR 2128, Jan. 22, 1991, as amended at 61 FR 36279, July 10, 1996; 62 FR 11759, Mar. 13, 1997; 68 FR 75388, Dec. 31, 2003]

§ 201.28 Duplicates of bonds or equivalents to be filed with Regional Supervisors.

Fully executed duplicates of bonds, trust fund agreements, and trust agreements maintained under the regulations in this part, and fully executed duplicates of all endorsements, amendments, riders, indemnity agreements, and other attachments thereto, and photographically reproduced copies of any letter of credit or amendment thereto, shall be filed with the Regional Supervisor for the region in which the registrant, packer, or person applying for registration resides, or in the case of a corporation, where the corporation has its home office: *Provided*, that if such registrant, packer, or person does not engage in business in such area, the foregoing documents shall be filed with the Regional Supervisor for the region in which the place of business of the registrant or packer or person is located.

(Approved by the Office of Management and Budget under control number 0580–0015)

[56 FR 2128, Jan. 22, 1991, as amended at 68 FR 75388, Dec. 31, 2003]

MARKET AGENCY, DEALER AND PACKER BONDS

§ 201.29 Market agencies, packers and dealers required to file and maintain bonds.

(a) Every market agency, packer, and dealer, except as provided in paragraph (d) of this section, and except packer buyers registered as dealers to purchase livestock for slaughter only, shall execute and maintain a reasonable bond on forms approved by the Administrator containing the appropriate condition clauses, as set forth in § 201.31 of the regulations, applicable to the activity or activities in which the person or persons propose to engage, to secure the performance of obligations

incurred by such market agency, packer, or dealer. No market agency, packer, or dealer required to maintain a bond shall conduct his operations unless there is on file and in effect a bond complying with the regulations in this part.

(b) Every market agency buying on a commission basis and every dealer buying for his own account or for the accounts of others shall file and maintain a bond. If a registrant operates as both a market agency buying on a commission basis and as a dealer, only one bond to cover both buying operations need be filed. Any person operating as a market agency selling on a commission basis and as a market agency buying on a commission basis or as a dealer shall file and maintain separate bonds to cover his selling and buying operations.

(c) Each market agency and dealer whose buying operations are cleared by another market agency shall be named as clearee in the bond filed and maintained by the market agency registered to provide clearing services. Each market agency selling livestock on a commission basis shall file and maintain its own bond.

(d) Every packer purchasing livestock, directly or through an affiliate or employee or a wholly-owned subsidiary, except those packers whose annual purchases do not exceed $500,000, shall file and maintain a reasonable bond. In the event a packer maintains a wholly-owned subsidiary or affiliate to conduct its livestock buying, the wholly-owned subsidiary or affiliate shall be registered as a packer buyer for its parent packer firm, and the required bond shall be maintained by the parent packer firm.

(7 U.S.C. 204, 228(a))

[48 FR 8806, Mar. 2, 1983]

§ 201.30 Amount of market agency, dealer and packer bonds.

(a) *Market agency selling livestock on commission.* To compute the required amount of bond coverage, divide the dollar value of livestock sold during the preceding business year, or the substantial part of that business year, in which the market agency did business, by the actual number of days on which livestock was sold. The divisor (the number of days on which livestock was sold) shall not exceed 130. The amount of bond coverage must be the next multiple of $5,000 above the amount so determined. When the computation exceeds $50,000, the amount of bond coverage need not exceed $50,000 plus 10 percent of the excess over $50,000, raised to the next $5,000 multiple. In no case shall the amount of bond coverage for a market agency selling on commission be less than $10,000 or such higher amount as required to comply with any State law.

(b) *Market agency buying on commission or dealer.* The amount of bond coverage must be based on the average amount of livestock purchased by the dealer or market agency during a period equivalent to 2 business days. To compute the required amount of bond coverage, divide the total dollar value of livestock purchased during the preceding business year, or substantial part of that business year, in which the dealer or market agency or both did business, by one-half the number of days on which business was conducted. The number of days in any business year, for purposes of this regulation, shall not exceed 260. Therefore, the divisor (one-half the number of days on which business was conducted) shall not exceed 130. The amount of the bond coverage must be the next multiple of $5,000 above the amount so determined. When the computation exceeds $75,000, the amount of bond coverage need not exceed $75,000 plus 10 percent of the excess over $75,000, raised to the next $5,000 multiple. In no case shall the amount of bond coverage be less than $10,000 or such higher amount as required to comply with any State law.

(c) *Market agency acting as clearing agency.* The amount of bond coverage must be based on the average amount of livestock purchased by all persons for whom the market agency served as a clearor during a period equivalent to 2 business days. To compute the required amount of bond coverage, divide the total dollar value of livestock purchased by all persons for whom the market agency served as a clearor during the preceding business year, or substantial part of that business year, in which the market agency acting as

clearing agency did business, by one-half the number of days on which business was conducted. The number of days in any business year, for purposes of this regulation, shall not exceed 260. Therefore, the divisor (one-half the number of days on which business was conducted) shall not exceed 130. The amount of bond coverage must be the next multiple of $5,000 above the amount so determined. When the computation exceeds $75,000, the amount of bond coverage need not exceed $75,000 plus 10 percent of the excess over $75,000, raised to the next $5,000 multiple. In no case shall the amount of bond coverage be less than $10,000 or such higher amount as required to comply with any State law.

(d) *Packer.* The amount of bond coverage must be based on the average amount of livestock purchased by the packer during a period equivalent to 2 business days. To compute the required amount of bond coverage, divide the total dollar value of livestock purchased during the preceding business year, or substantial part of that business year, in which the packer did business, by one-half the number of days on which business was conducted. The number of days in any business year, for purposes of this regulation, shall not exceed 260. Therefore, the divisor (one-half the number of days on which business was conducted) shall not exceed 130. The amount of the bond coverage must be the next multiple of $5,000 above the amount so determined. In no case shall the amount of bond coverage for a packer be less than $10,000.

(e) If a person applying for registration as a market agency or dealer has been engaged in the business of handling livestock before the date of the application, the value of the livestock handled, if representative of future operations, must be used in computing the required amount of bond coverage. If the applicant for registration is a successor in business to a registrant formerly subject to these regulations, the amount of bond coverage of the applicant must be at least that amount required of the prior registrant, unless otherwise determined by the Administrator. If a packer becomes subject to these regulations, the value of livestock purchased, if representative of future operations, must be used in computing the required amount of bond coverage. If a packer is a successor in business to a packer formerly subject to these regulations, the amount of bond coverage of the successor must be at least that amount required of the prior packer, unless otherwise determined by the Administrator.

(f) Whenever the Administrator has reason to believe that a bond is inadequate to secure the performance of the obligations of the market agency, dealer or packer covered thereby, the Administrator shall notify such person to adjust the bond to meet the requirements the Administrator determines to be reasonable.

(7 U.S.C. 204, 228(a))

[48 FR 8806, Mar. 2, 1983]

§ 201.31 Conditions in market agency, dealer and packer bonds.

Each market agency, dealer and packer bond shall contain conditions applicable to the activity or activities in which the person or persons named as principal or clearees in the bond propose to engage, which conditions shall be as follows or in terms to provide equivalent protection:

(a) *Condition Clause No. 1: When the principal sells livestock for the accounts of others.* If the said principal shall pay when due to the person or persons entitled thereto the gross amount, less lawful charges, for which all livestock is sold for the accounts of others by said principal.

(b) *Condition Clause No. 2: When the principal buys livestock for his own account or for the accounts of others.* If the said principal shall pay when due to the person or persons entitled thereto the purchase price of all livestock purchased by said principal for his own account or for the accounts of others, and if the said principal shall safely keep and properly disburse all funds, if any, which come into his hands for the purpose of paying for livestock purchased for the accounts of others.

(c) *Condition Clause No. 3: When the principal clears other registrants buying livestock and thus is responsible for the obligations of such other registrants.* If

the said principal, acting as a clearing agency responsible for the financial obligations of other registrants engaged in buying livestock, viz: (Insert here the names of such other registrants as they appear in the application for registration), or if such other registrants, shall (1) pay when due to the person or persons entitled thereto the purchase price of all livestock purchased by such other registrants for their own account or for the accounts of others; and (2) safely keep and properly disburse all funds coming into the hands of such principal or such other registrants for the purpose of paying for livestock purchased for the accounts of others.

(d) *Condition Clause No. 4: When the principal buys livestock for his own account as a packer.* If the said principal shall pay when due to the person or persons entitled thereto the purchase price of all livestock purchased by said principal for his own account.

[47 FR 32695, July 29, 1982]

§ 201.32 Trustee in market agency, dealer and packer bonds.

Bonds may be in favor of a trustee who shall be a financially responsible, disinterested person satisfactory to the Administrator. State officials, secretaries or other officers of livestock exchanges or of similar trade associations, attorneys at law, banks and trust companies, or their officers, are deemed suitable trustees. If a trustee is not designated in the bond and action is taken to recover damages for breach of any condition thereof, the Administrator shall designate a person to act as trustee. In those States in which a State official is required by statute to act or has agreed to act as trustee, such official shall be designated by the Administrator as trustee when a designation by the Administrator becomes necessary.

[41 FR 53774, Dec. 9, 1976]

§ 201.33 Persons damaged may maintain suit; filing and notification of claims; time limitations; legal expenses.

Each bond and each bond equivalent filed pursuant to the regulations in this part shall contain provisions that:

(a) Any person damaged by failure of the principal to comply with any condition clause of the bond or bond equivalent may maintain suit to recover on the bond or bond equivalent even though such person is not a party named in the bond or bond equivalent;

(b) Any claim for recovery on the bond or bond equivalent must be filed in writing with either the surety, if any, or the trustee, if any, or the Administrator, and whichever of these parties receives such a claim shall notify the other such party or parties at the earliest practical date;

(c) The Administrator is authorized to designate a trustee pursuant to § 201.32;

(d) The surety on the bond, or the trustee on the bond equivalent, as the case may be, shall not be liable to pay any claim if it is not filed in writing within 60 days from the date of the transaction on which the claim is based or if suit thereon is commenced less than 120 days or more than 547 days from the date of the transaction on which the claim is based;

(e) The proceeds of the bond or bond equivalent, as the case may be, shall not be used to pay fees, salaries, or expenses for legal representation of the surety or the principal.

[56 FR 2128, Jan. 22, 1991]

§ 201.34 Termination of market agency, dealer and packer bonds.

(a) Each bond shall contain a provision requiring that, prior to terminating such bond, at least 30 days notice in writing shall be given to the Administrator, Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs), U.S. Department of Agriculture, Washington, DC 20250, by the party terminating the bond. Such provision may state that in the event the surety named therein writes a replacement bond for the same principal, the 30-day notice requirement may be waived and the bond will be terminated as of the effective date of the replacement bond.

(b) Each bond filed by a market agency who clears other registrants who are named in the bond shall contain a provision requiring that, prior to terminating the bond coverage of any clearee named therein, at least 30 days notice in writing shall be given to the

Administrator, Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs), U.S. Department of Agriculture, Washington, DC 20250, by the surety. Such written notice shall be in the form of a rider or endorsement to be attached to the bond of the clearing agency.

(c) Each trust fund agreement and trust agreement shall contain a provision requiring that, prior to terminating such agreement, at least 30 days notice in writing shall be given to the Administrator, Grain Inspection, Packers and Stockyards Administration, U.S. Department of Agriculture, Washington, DC 20250, by the party terminating the agreement. Such provision shall state that in the event the principal named therein files an acceptable bond or bond equivalent to replace the agreement, the 30-day notice requirement may be waived and the agreement will be terminated as of the effective date of the replacement bond or bond equivalent.

(Approved by the Office of Management and Budget under control number 0580–0015)

[47 FR 32695, July 29, 1982, as amended at 54 FR 26349, June 23, 1989; 61 FR 36279, July 10, 1996; 68 FR 75388, Dec. 31, 2003]

PROCEEDS OF SALE

§ 201.39 Payment to be made to consignor or shipper by market agencies; exceptions.

(a) No market agency shall, except as provided in paragraph (b) of this section, pay the net proceeds or any part thereof, arising from the sale of livestock consigned to it for sale, to any person other than the consignor or shipper of such livestock except upon an order from the Secretary or a court of competent jurisdiction, unless (1) such market agency has reason to believe that such person is the owner of the livestock, (2) such person holds a valid, unsatisfied mortgage or lien upon the particular livestock, or (3) such person holds a written order authorizing such payment executed by the owner at the time of or immediately following the consignment of such livestock: *Provided,* That this paragraph shall not apply to deductions made from sales proceeds for the purpose of financing promotion and research activities, including educational activities, relating to livestock, meat, and other products covered by the Act, carried out by producer-sponsored organizations.

(b) The net proceeds arising from the sale of livestock, the ownership of which has been questioned by a market agency duly authorized to inspect brands, marks, and other identifying characteristics of livestock may be paid in accordance with the directions of such brand inspection agency if the laws of the State from which such livestock originated or was shipped to market make provision for payment of the proceeds in the manner directed by the brand inspection agency and if the market agency to which the livestock was consigned, and the consignor or consignors concerned, are unable to establish the ownership of the livestock within a reasonable period of time, not to exceed 60 days after sale.

(7 U.S.C. 181 *et seq.*)

[19 FR 4528, July 22, 1954, as amended at 28 FR 7218, July 13, 1963; 44 FR 45361, Aug. 2, 1979]

§ 201.42 Custodial accounts for trust funds.

(a) *Payments for livestock are trust funds.* Each payment that a livestock buyer makes to a market agency selling on commission is a trust fund. Funds deposited in custodial accounts are also trust funds.

(b) *Custodial accounts for shippers' proceeds.* Every market agency engaged in selling livestock on a commission or agency basis shall establish and maintain a separate bank account designated as ''Custodial Account for Shippers' Proceeds,'' or some similar identifying designation, to disclose that the depositor is acting as a fiduciary and that the funds in the account are trust funds.

(c) *Deposits in custodial accounts.* The market agency shall deposit in its custodial account before the close of the next business day (the next day on which banks are customarily open for business whether or not the market agency does business on that day) after livestock is sold (1) the proceeds from the sale of livestock that have been collected, and (2) an amount equal to the proceeds receivable from the sale of

livestock that are due from (i) the market agency, (ii) any owner, officer, or employee of the market agency, and (iii) any buyer to whom the market agency has extended credit. The market agency shall thereafter deposit in the custodial account all proceeds collected until the account has been reimbursed in full, and shall, before the close of the seventh day following the sale of livestock, deposit an amount equal to all the remaining proceeds receivable whether or not the proceeds have been collected by the market agency.

(d) *Withdrawals from custodial accounts.* The custodial account for shippers' proceeds shall be drawn on only for payment of (1) the net proceeds to the consignor or shipper, or to any person that the market agency knows is entitled to payment, (2) to pay lawful charges against the consignment of livestock which the market agency shall, in its capacity as agent, be required to pay, and (3) to obtain any sums due the market agency as compensation for its services.

(e) *Accounts and records.* Each market agency shall keep such accounts and records as will disclose at all times the handling of funds in such custodial accounts for shippers' proceeds. Accounts and records must at all times disclose the name of the consignors and the amount due and payable to each from funds in the custodial account for shippers' proceeds.

(f) *Insured banks.* Such custodial accounts for shippers' proceeds must be established and maintained in banks whose deposits are insured by the Federal Deposit Insurance Corporation.

(g) *Certificates of deposit and/or savings accounts.* Funds in a custodial account for shippers' proceeds may be maintained in an interest-bearing savings account and/or invested in one or more certificates of deposit, to the extent that such deposit or investment does not impair the ability of the market agency to meet its obligations to its consignors. The savings account must be properly designated as a party of the custodial account of the market agency in its fiduciary capacity as trustee of the custodial funds and maintained in the same bank as the custodial account. The certificates of deposit, as property of the custodial account, must be issued by the bank in which the custodial account is kept and must be made payable to the market agency in its fiduciary capacity as trustee of the custodial funds.

(Approved by the Office of Management and Budget under control number 0580–0015)

[47 FR 32696, July 29, 1982, as amended at 54 FR 26349, June 23, 1989; 68 FR 75388, Dec. 31, 2003]

ACCOUNTS AND RECORDS

§ 201.43 Payment and accounting for livestock and live poultry.

(a) *Market agencies to make prompt accounting and transmittal of net proceeds.* Each market agency shall, before the close of the next business day following the sale of any livestock consigned to it for sale, transmit or deliver to the consignor or shipper of the livestock, or the duly authorized agent, in the absence of any knowledge that any other person, or persons, has any interest in the livestock, the net proceeds received from the sale and a true written account of such sale, showing the number, weight, and price of each kind of animal sold, the date of sale, the commission, yardage, and other lawful charges, and such other facts as may be necessary to complete the account and show fully the true nature of the transaction.

(b) *Prompt payment for livestock and live poultry—terms and conditions.* (1) No packer, market agency, or dealer shall purchase livestock for which payment is made by a draft which is not a check, unless the seller expressly agrees in writing before the transaction that payment may be made by such a draft. (In cases of packers whose average annual purchases exceed $500,000, and market agencies and dealers acting as agents for such packers, see also § 201.200).

(2)(i) No packer, market agency, or dealer purchasing livestock for cash and not on credit, whether for slaughter or not for slaughter, shall mail a check in payment for the livestock unless the check is placed in an envelope with proper first class postage prepaid and properly addressed to the seller or such person as he may direct, in a post office, letter box, or other receptacle

regularly used for the deposit of mail for delivery, from which such envelope is scheduled to be collected (A) before the close of the next business day following the purchase of livestock and transfer of possession thereof, or (B) in the case of a purchase on a ''carcass'' or ''grade and yield'' basis, before the close of the first business day following determination of the purchase price.

(ii) No packer, market agency, or dealer purchasing livestock for slaughter, shall mail a check in payment for the livestock unless (A) the check is made available for actual delivery and the seller or his duly authorized representative is not present to receive payment, at the point of transfer of possession of such livestock, on or before the close of the next business day following the purchase of the livestock and transfer of possession thereof, or, in the case of a purchase on a ''carcass'' or ''grade and yield'' basis, on or before the close of the first business day following determination of the purchase price; or unless (B) the seller expressly agrees in writing before the transaction that payment may be made by such mailing of a check.

(3) Any agreement referred to in paragraph (b) (1) or (2) of this section shall be disclosed in the records of any market agency or dealer selling such livestock, and in the records of the packer, market agency, or dealer purchasing such livestock, and retained by such person for such time as is required by any law, or by written notice served on such person by the Administrator, but not less than two calendar years from the date of expiration thereof.

(4) No packer, live poultry dealer, market agency, or livestock dealer shall as a condition to its purchase of livestock or poultry, impose, demand, compel or dictate the terms or manner of payment, or attempt to obtain a payment agreement from a seller through any threat of retaliation or other form of intimidation.

(c) *Purchaser to promptly reimburse agents.* Each packer, market agency, or dealer who utilizes or employs an agent to purchase livestock for him, shall, in transactions where such agent uses his own funds to pay for livestock purchased on order, transmit or deliver to such agent the full amount of the purchase price before the close of the next business day following receipt of notification of the payment of such purchase price, unless otherwise expressly agreed between the parties before the purchase of the livestock. Any such agreement shall be disclosed in the records of the principal and in the records of any market agency or dealer acting as such agent.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 228, 7 U.S.C. 222, and 15 U.S.C. 46)

[49 FR 6083, Feb. 17, 1984, as amended at 49 FR 8235, Mar. 6, 1984; 54 FR 16355, Apr. 24, 1989; 68 FR 75388, Dec. 31, 2003]

§ 201.44 Market agencies to render prompt accounting for purchases on order.

Each market agency shall, promptly following the purchase of livestock on a commission or agency basis, transmit or deliver to the person for whose account such purchase was made, or the duly authorized agent, a true written account of the purchase showing the number, weight, and price of each kind of animal purchased, the names of the persons from whom purchased, the date of purchase, the commission and other lawful charges, and such other facts as may be necessary to complete the account and show fully the true nature of the transaction.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 181 *et seq.*)

[44 FR 45360, Aug. 2, 1979, as amended at 54 FR 26349, June 23, 1989; 68 FR 75388, Dec. 31, 2003]

§ 201.45 Market agencies to make records available for inspection by owners, consignors, and purchasers.

Each market agency engaged in the business of selling or buying livestock on a commission or agency basis shall, on request from an owner, consignor, or purchaser, make available copies of bills covering charges paid by such market agency for and on behalf of the owner, consignor, or purchaser which were deducted from the gross proceeds of the sale of livestock or added to the

purchase price thereof when accounting for the sale or purchase.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 181 *et seq.;* Pub. L. 96–511, 94 Stat. 2812 (44 U.S.C. 3501 *et seq.*))

[19 FR 4528, July 22, 1954, as amended at 44 FR 45361, Aug. 2, 1979; 47 FR 746, Jan. 7, 1982; 54 FR 26349, June 23, 1989; 68 FR 75388, Dec. 31, 2003]

§ 201.49 Requirements regarding scale tickets evidencing weighing of livestock, live poultry, and feed.

(a) When livestock, poultry or feed is weighed for the purpose of purchase, sale, acquisition, or settlement, a scale ticket must be issued which must be serially numbered and used in numerical sequence. Sufficient copies must be executed and provided to all parties to the transaction. Unused and partially executed scale tickets must not be left exposed or accessible to other parties and, except in feed mills, must be kept under lock when the weigher is not at the scale. In instances where the weight values are automatically recorded directly on the account of purchase, account of sale, or other basic transaction record, this record may serve in place of a scale ticket.

(b) *Livestock.* When livestock is weighed for the purpose of purchase or sale, or when livestock is purchased on a carcass weight or carcass grade and weight basis, the live or hot carcass weights must be recorded using a scale equipped with a printing device, and such printed weights must be retained as part of the person or firm's business records to substantiate settlement on each transaction. In instances where the weight values are automatically recorded directly on the account of purchase, account of sale, or other basic transaction record, this record may serve in place of a scale ticket. Scale tickets or other basic transaction records issued under this section must show:

(1) The name and location of the agency performing the weighing service;

(2) The date of the weighing;

(3) The name of the buyer and seller or consignor, or a designation by which they may be readily identified;

(4) The number of head;

(5) Kind of livestock;

(6) Actual weight of each draft of livestock; and

(7) The name, initials, or identification number of the person who weighed the livestock, or if required by State law, the signature of the weigher, except for an automated weighing system where a weigher is not stationed at the scale.

(c) *Poultry.* When live poultry is weighed for the purpose of purchase, sale, acquisition, or settlement by a live poultry dealer, the scale ticket or other basic transaction record must show:

(1) The name of the agency performing the weighing service;

(2) The name of the live poultry dealer;

(3) The name and address of the grower or seller, and purchaser, or a designation by which they may be readily identified;

(4) The name, initials, or identification number of the person who weighed the poultry, or if required by State law, the signature of the weigher;

(5) The city and state in which the scale is located, and, if more than one scale is used to obtain the weight of poultry within the same facility, the identity of the scale;

(6) The zero balance for both the gross weight and tare weight;

(7) The date and time zero balance was determined;

(8) The gross weight, tare weight, and net weight;

(9) The date and time gross weight and tare weight are determined;

(10) The number of poultry weighed;

(11) The weather conditions;

(12) Whether the driver was on or off the truck at the time of weighing, if applicable; and

(13) The license number or other identification numbers on the truck and trailer, if weighed together, or trailer if only the trailer is weighed; *provided,* that when live poultry is weighed on a scale other than a vehicle scale, the scale ticket or other basic transaction record need not show the information specified in paragraphs (c)(11) and (c)(12) of this section.

(d) *Feed.* Whenever feed is weighed and the weight of the feed is a factor in determining payment or settlement to

a livestock producer or poultry grower, the scale ticket or other basic transaction record must show:

(1) The name of the agency performing the weighing service, or the name and location of the firm responsible for supplying the feed;

(2) The name and address of the livestock producer or poultry grower, or a designation by which they may be readily identified;

(3) The name, initials or identification number of the person who weighed the feed, or if required by State law, the signature of the weigher;

(4) The city and state in which the scale is located, and, if a facility has more than one scale on which feed is weighed, the identity of the scale;

(5) The zero balance; *provided* that when using a vehicle scale to weigh feed for more than one producer or grower on the same multi-compartment truck, the preceding producer's or grower's gross weight can be used for the next producer's or grower's tare weight without printing a zero balance, and repeated until the unit is full;

(6) The date and time zero balance was determined;

(7) The gross weight, tare weight, and net weight of each lot assigned to an individual producer or grower, if applicable;

(8) The date and time gross weight and, if applicable, tare weight, are determined;

(9) The identification of each lot assigned to an individual producer or grower by vehicle or trailer compartment number and seal number, if applicable;

(10) Whether the driver was on or off the truck at the time of weighing, if applicable; and

(11) The license number or other identification numbers on the truck and trailer, if weighed together, or trailer if only the trailer is weighed, if applicable.

[78 FR 51663, Aug. 21, 2013]

TRADE PRACTICES

§ 201.53 Persons subject to the Act not to circulate misleading reports about market conditions or prices.

No packer, swine contractor, live poultry dealer, stockyard owner, market agency, or dealer shall knowingly make, issue, or circulate any false or misleading reports, records, or representation concerning the market conditions or the prices or sale of any livestock, meat, or live poultry.

[73 FR 62440, Oct. 21, 2008]

§ 201.55 Purchases, sales, acquisitions, payments and settlements to be made on actual weights.

(a) Except as provided in paragraph (b) of this section, whenever livestock or live poultry is bought, sold, acquired, paid, or settled on a weight basis, or whenever the weight of feed is a factor in determining payment or settlement to a livestock grower or poultry grower by a stockyard owner, market agency, dealer, packer, or live poultry dealer when livestock or poultry is produced under a growing arrangement, payment or settlement shall be on the basis of the actual weight of the livestock, live poultry, and/or feed shown on the scale ticket. If the actual weight used is not obtained on the date and at the place of transfer of possession, this information shall be disclosed with the date and location of the weighing on the accountings, bills, or statements issued. Any adjustment to the actual weight shall be fully and accurately explained on the accountings, bills, or statements issued, and records shall be maintained to support such adjustment.

(b) Whenever the weight of feed is a factor in determining payment or settlement to such livestock grower or poultry grower when the livestock or poultry is produced under a livestock or poultry growing arrangement, any feed that is picked up from or returned by a livestock grower or poultry grower must be weighed or its weight must be reasonably determined. When feed is picked up or returned and not weighed, the stockyard owner, market agency, dealer, packer, or live poultry dealer must document that the method used reasonably determines weight and is mutually acceptable to it and the livestock grower or poultry grower. The stockyard owner, market agency, dealer, packer, or live poultry dealer must

document and account for the picked up or returned feed weight.

(Approved by the Office of Management and Budget under control number 0580–0015)

[65 FR 17762, Apr. 5, 2000]

§ 201.56 Market agencies selling on commission; purchases from consignment.

(a) *Livestock to be sold openly at highest available bid.* Every market agency engaged in the business of selling livestock on a commission or agency basis shall sell the livestock consigned to it openly, at the highest available bid, and in such a manner as to best promote the interest of each consignor.

(b) *Purchases from consignment.* No market agency engaged in the business of selling livestock on a commission basis shall purchase livestock from consignments, and no such market agency shall permit its owners, officers, agents, employees or any firm in which such market agency or its owners, officers, agents, or employees have an ownership or financial interest to purchase livestock consigned to such market agency, without first offering the livestock for sale in an open and competitive manner to other available buyers, and then only at a price higher than the highest available bid on such livestock.

(c) *Key employees not to purchase livestock out of consignments.* No market agency engaged in selling livestock on commission shall permit its auctioneers, weighmasters, or salesmen to purchase livestock out of consignment for any purpose for their own account, either directly or indirectly.

(d) *Purchase from consignments; disclosure required.* When a market agency purchases consigned livestock or sells consigned livestock to any owner, officer, agent, employee, or any business in which such market agency, owner, officer, agent, or employee has an ownership or financial interest, the market agency shall disclose on the account of sale the name of the buyer and the nature of the relationship existing between the market agency and the buyer.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 228, 7 U.S.C. 222, and 15 U.S.C. 46)

[49 FR 6084, Feb. 17, 1984, as amended at 49 FR 13003, Apr. 2, 1984; 58 FR 52886, Oct. 13, 1993; 68 FR 75388, Dec. 31, 2003]

§ 201.61 Market agencies selling or purchasing livestock on commission; relationships with dealers.

(a) *Market agencies selling on commission.* No market agency selling consigned livestock shall enter into any agreement, relationship or association with dealers or other buyers which has a tendency to lessen the loyalty of the market agency to its consignors or impair the quality of the market agency's selling services. No market agency selling livestock on commission shall provide clearing services for any independent dealer who purchases livestock from consignment to such market agency without disclosing, on the account of sale to the consignor, the name of the buyer and the nature of the financial relationship between the buyer and the market agency.

(b) *Market agencies buying on commission.* No market agency purchasing livestock on commission shall enter into any agreement, relationship, or association with dealers or others which will impair the quality of the buying services furnished to its principals. No market agency purchasing livestock on commission shall, in filling orders, purchase livestock from a dealer whose operations it clears or finances without disclosing the relationship between the market agency and dealer to its principals on the accountings furnished to the principals.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 228, 7 U.S.C. 222, and 15 U.S.C. 46)

[49 FR 6085, Feb. 17, 1984, as amended at 60 FR 42779, Aug. 17, 1995; 68 FR 75388, Dec. 31, 2003]

§ 201.67 Packers not to own or finance selling agencies.

No packer subject to the Act shall have an ownership interest in, finance, or participate in the management or operation of a market agency selling

livestock on a commission basis, nor shall such a market agency permit a packer to have an ownership interest in, finance, or participate in the management or operation of such market agency.

(7 U.S.C. 228, 228b, 222, 15 U.S.C. 46)

[49 FR 32844, Aug. 17, 1984]

§ 201.69 Furnishing information to competitor buyers.

No packer, dealer, or market agency, in connection with transactions subject to the provisions of the act, shall, in person, or through employed buyers, for the purpose of restricting or limiting competition, manipulating livestock prices, or controlling the movement of livestock, prior to, or during the conduct of, his buying operations: (a) Furnish competitor packers, dealers, market agencies, or their buyers or representatives, similarly engaged in buying livestock, with information concerning his proposed buying operations, such as the species, classes, volume of livestock to be purchased, or prices to be paid; or (b) furnish any other buying information to competitor buyers.

[19 FR 4531, July 22, 1954, as amended at 24 FR 3183, Apr. 24, 1959]

§ 201.70 Restriction or limitation of competition between packers and dealers prohibited.

Each packer and dealer engaged in purchasing livestock, in person or through employed buyers, shall conduct his buying operations in competition with, and independently of, other packers and dealers similarly engaged.

[24 FR 3183, Apr. 24, 1959]

SERVICES

§ 201.71 Scales and or Electronic Evaluation Devices or Systems; accurate weights and measures, repairs, adjustments or replacements after inspection.

(a) All scales used by stockyard owners, swine contractors, market agencies, dealers, packers, and live poultry dealers to weigh livestock, livestock carcasses, live poultry, or feed for the purposes of purchase, sale, acquisition, payment, or settlement shall be installed, maintained, and operated to ensure accurate weights. All electronic evaluation devices or systems for measuring the composition or quality constituents of live animals, livestock and poultry carcasses, and individual cuts of meat or a combination thereof for the purpose of determining value shall be installed, maintained, and operated to ensure accuracy. Such scales or electronic evaluation devices or systems shall meet applicable requirements contained in the General Code, Scales Code, Weights Code, and Electronic Livestock, Meat, and Poultry Evaluation Systems and/or Devices Code of the NIST Handbook 44. The 2013 edition of the National Institute of Standards and Technology (NIST) Handbook 44, ''Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices'' is hereby incorporated by reference and was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of approval and a notice of any change in these materials will be published in the FEDERAL REGISTER. All approved material is available for inspection at USDA, GIPSA, P&SP, 1400 Independence Ave. SW., Washington, DC 20250, 202–720–7363 and is for sale by the National Conference of Weights and Measures (NCWM), 1135 M Street, Suite 110, Lincoln, Nebraska, 68508. Information on this material may be obtained from NCWM by calling 402–434–4880, by emailing *info@ncwm.net*, or on the Internet at *http://www.nist.gov/owm*. It is also available for inspection at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(b) All scales used by stockyard owners, swine contractors, market agencies, dealers, packers, and live poultry dealers to weigh livestock, livestock carcasses, live poultry, or feed for the purpose of purchase, sale, acquisition, payment, or settlement of livestock or live poultry and all scales used for the purchase, sale acquisition, payment, or

settlement of livestock on a carcass weight basis shall be equipped with a printing device which shall record weight values on a scale ticket or other document.

(c) All vehicle scales used to weigh livestock, live poultry, or feed for purposes of purchase, sale, acquisition, payment, or settlement of livestock or live poultry shall be of sufficient length and capacity to weigh the entire vehicle as a unit: Provided, That a trailer may be uncoupled from the tractor and weighed as a single unit.

(d) No scales shall be operated or used by any stockyard owners, swine contractors, market agencies, dealers, packers, or live poultry dealers to weigh livestock, livestock carcasses, live poultry, or feed for the purposes of purchase, sale, acquisition, payment, or settlement of livestock, livestock carcasses or live poultry unless it has been found upon test and inspection, as specified in § 201.72, to be in a condition to give accurate weight. If a scale is inspected or tested and adjustments or replacements are made to a scale, it shall not be used until it has been inspected and tested and determined to meet all accuracy requirements specified in the regulations in this section.

[65 FR 17763, Apr. 5, 2000, as amended at 69 FR 18803, Apr. 9, 2004; 74 FR 53640, Oct. 20, 2009; 79 FR 23893, Apr. 29, 2014; 79 FR 32859, June 9, 2014]

§ 201.72 Scales; testing of.

(a) As a stockyard owner, swine contractor, market agency, dealer, packer, or live poultry dealer who weighs livestock, live poultry, or feed for purposes of purchase, sale, acquisition, payment, or settlement of livestock or live poultry, or who weighs livestock carcasses for the purpose of purchase on a carcass weight basis, or who furnishes scales for such purposes, you must have your scales tested by competent persons at least twice during each calendar year. You must complete the first of the two scale tests between January 1 and June 30 of the calendar year. The remaining scale test must be completed between July 1 and December 31 of the calendar year. You must have a minimum period of 120 days between these two tests. More frequent testing will be required in cases where the scale does not maintain accuracy between tests. *Except that* if scales are used on a limited seasonal basis (during any continuous 8-month period) for purposes of purchase, sale, acquisition, payment or settlement, the stockyard owner, swine contractor, market agency, dealer, live poultry dealer, or packer using such scales may use the scales within a 8-month period following each test.

(b) As a stockyard owner, swine contractor, market agency, dealer, packer, or live poultry dealer who weighs livestock, livestock carcasses, live poultry, or feed for purposes of purchase, sale, acquisition, payment, or settlement of livestock, livestock carcasses or live poultry, you must furnish reports of tests and inspections on forms approved by the Administrator. You must retain one copy of the test and inspection report for yourself, and file a second copy with the P&SP regional office for the geographical region where the scale is located.

(c) When scales used for weighing livestock, livestock carcasses, live poultry, or feed are tested and inspected by a State agency, municipality, or other governmental subdivision, the forms used by such agency for reporting such scale tests and inspections may be accepted in lieu of the forms approved for this same purpose by the Administrator if the forms contain substantially the same information.

[76 FR 3487, Jan. 20, 2011; 76 FR 50881, Aug. 17, 2011]

§ 201.73 Scale operators to be qualified.

Stockyard owners, market agencies, dealers, packers, and live poultry dealers shall employ qualified persons to operate scales for weighing livestock, livestock carcasses, live poultry, or feed for the purposes of purchase, sale, acquisition, payment, or settlement of livestock, livestock carcasses, or live poultry, and they shall require such employees to operate the scales in accordance with the regulations in this part.

[65 FR 17763, Apr. 5, 2000]

§ 201.73–1 Instructions for weighing livestock.

Stockyard operators, market agencies, dealers, and packers who operate scales on which livestock is weighed in purchase or sales transactions are responsible for the accurate weighing of such livestock. They shall supply copies of the instructions in this section to all persons who perform weighing operations for them and direct such person to familiarize themselves with the instructions and to comply with them at all times. This section shall also apply to any additional weighers who are employed at any time. Weighers must acknowledge their receipt of these instructions and agree to comply with them, by signing in duplicate, P&SA Form 215 provided by the Packers and Stockyards Programs. One copy of the form is to be filed with a regional office of the Packers and Stockyards Programs and the other retained by the agency employing the weighers.

(a) *Balancing the empty scale.* (1) The empty scale shall be balanced each day before weighing begins, and maintained in correct balance which weighing operations continue. The zero balance shall be verified at intervals of not more than 15 drafts or 15 minutes, whichever is completed first. In addition, the zero balance of the scale shall be verified whenever a weigher resumes weighing duties after an absence from the scale and also whenever a load exceeding half the scale capacity or 10,000 pounds (whichever is less) has been weighed and is followed by a load of less than 1,000 pounds, verification to occur before the weighing of the load of less than 1,000 pounds.

(2) The time at which the empty scale is balanced or its zero balance verified shall be recorded on scale tickets or other permanent records. Balance tickets must be filed with other scale tickets issued on that date.

(3) Before balancing the empty scale, the weigher shall assure himself that the scale gates are closed and that no persons or animals are on the scale platform or in contact with the stock rack, gates, or platform. If the scale is balanced with persons on the scale platform, the zero balance shall be verified whenever there is a change in such persons. When the scale is properly balanced and ready for weighing, the weigher shall so indicate by an appropriate signal.

(4) Weighbeam scales shall be balanced by first seating each poise securely in its zero notch and then moving the balance ball to such position that a correct zero balance is obtained. A scale equipped with a balance indicator is correctly balanced when the pointer comes to rest at zero. A scale not equipped with a balance indicator is correctly balanced if the weighbeam, when released at the top or bottom of the trig loop, swings freely in the trig loop in such manner that it will come to rest at the center of the trig loop.

(5) Dial scales shall be balanced by releasing all drop weights and operating the balance ball or other balancing device to obtain a correct zero balance. The indicator must visually indicate zero on the dial and the ticket printer must record a correct zero balance.

(6) Electronic digital scales should be properly warmed up before use. In most cases, it is advisable to leave the electric power on continuously. The zero load balance shall be verified by recording the zero balance on a scale ticket. The main indicating element and the remote visual weight display shall indicate zero when the balance is verified. The proper procedure for balancing this type of scale will vary according to the manufacturer. Refer to the operator's manual for specific instructions.

(b) *Weighing the load.* (1) Before weighing a draft of livestock, the weigher shall assure himself that the entire draft is on the scale platform with the gates closed and that no persons or animals off the scale are in contact with the platform, gates, or stock rack.

(i) On a weighbeam scale with a balance indicator, the weight of a draft shall be determined by seating the poises at such positions that the pointer will come to rest within the central target area or within ¼ (0.25) inch of the zero mark.

(ii) On a weighbeam scale without a balance indicator, the weight shall be determined by seating the poises at such positions that the weighbeam,

when released from the top or bottom of the trig loop, will swing freely and come to rest at the approximate center of the trig loop.

(iii) On a dial scale, the weight is indicated automatically when the indicator moves around the dial face and comes to rest.

(iv) On an electronic digital scale, the weight of a draft is indicated automatically when the weight value indicated stabilized.

(2) The correct weight of a livestock draft is the value in pounds indicated when a correct load balance is obtained. The weigher should always concentrate his attention upon the beam tip, balance indicator or dial indicator while weighing and not concern himself with reading the visible weight indications until correct load balance is obtained. On electronic digital scales, the weigher should concentrate on the pulsing or flickering of weight values to assure that the unit indicates a stable weight before activating the print button.

(c) *Recording the weight.* (1) The weight of each draft shall be recorded immediately after the load balance is obtained and before any poises are moved or the load is removed from the scale platform. The weigher shall make certain that the printed weight record agrees with the weight value visually indicated when correct load balance is obtained. He shall also assure himself that the printed weight value is distinct and legible.

(2) The weight printing device on a scale shall be operated only to produce a printed or impressed record of the weight value while the livestock load is on the scale and correctly balanced. If the weight value is not printed clearly and correctly, the ticket shall be marked void and a new one printed before the livestock is removed from the scale.

(d) *Scale tickets.* (1) Scale tickets used to record the weight values of livestock in purchase or sales transactions shall be used, at any given scale, in the order of their consecutive serial numbers unless otherwise marked to show the order of their use. All tickets shall show the date of the weighing and the name or initials of the weigher performing the weighing service.

(2) No scale tickets shall be destroyed or otherwise disposed of because they are soiled, damaged, incorrectly executed, or voided. They shall be preserved and filed to comprise a complete serial number sequence.

(3) No scale ticket shall be used to record the weight of a livestock draft for ''catch-weight,'' inventory, transportation charge or other nonsale purposes unless the ticket is clearly marked to show why the weight was determined.

(4) When weight values are recorded by means of automatic recording equipment directly on the accounts of sale or other basic records, such record may serve in lieu of a scale ticket.

(e) *Weigher's responsibilities.* (1) The primary responsibility of a weigher is to determine and accurately record the weight of livestock drafts without prejudice or favor to any person or agency and without regard for livestock ownership, price, condition, fill, shrink, or other considerations. A weigher shall not permit the representations or attitudes of any persons or agencies to influence his judgment or action in performing his duties.

(2) Unused scale tickets, or those which are partially executed but without a printed weight value, shall not be left exposed or accessible to unauthorized personnel. All such tickets shall be kept under lock when the weigher is not at his duty station.

(3) Accurate weighing and correct weight recording require that a weigher shall not permit his operations to be hurried to the extent that inaccurate weights or incorrect weight records may result. Each draft of livestock must be weighed accurately to the nearest minimum weight value that can be indicated or recorded. Manual operations connected with balancing, weighing, and recording shall be performed with the care necessary to prevent damage to the accurately machined and adjusted parts of weighbeams, poises, and printing devices.

(4) Livestock owners, buyers, or others having legitimate interest in a livestock draft must be permitted to observe the balancing, weighing, and recording procedures, and a weigher shall not deny them that right or withhold

from them any information pertaining to the weight of that draft. He shall check the zero balance of the scale or reweigh a draft of livestock when requested by such parties.

(f) *Sensitivity control.* (1) A scale must be sensitive in response to platform loading if it is to yield accurate weights. It, therefore, is the duty of a weigher to assure himself that interferences, weighbeam friction, or other factors do not impair sensitivity. He should satisfy himself, at least twice each day, that the scale is sufficiently sensitive, and if the following requirements are not met, he should report the facts to his superior or employer immediately.

(2) A weighbeam scale with a balance indicator is sufficiently sensitive if, when the scale is balanced with the pointer at the center of the target, movement of the fractional poise one graduation will change the indicator rest point ¼ inch (0.25) or the width of the central target area, whichever is greater.

(3) A weighbeam scale without a balance indicator is sufficiently sensitive if, when the scale is balanced with the weighbeam at the center of the trig loop, movement of the fractional poise two graduations will cause the weighbeam to come to rest at the bottom of the trig loop.

(4) Adjustable damping devices are incorporated in balance indicators and in dial scales to absorb the effects of load impact and assist in bringing the indicator to rest. The weigher should be familiar with the location and adjustment of these damping devices and should keep them adjusted so that the pointer will oscillate freely through at least one complete cycle of movement before coming to rest at its original position.

(5) Friction at weighbeam bearings may reduce the sensitivity of the scale, cause sluggish weighbeam action and affect weighing accuracy. A weigher should inspect the weighbeam assembly daily to make certain that there is clearance between the weighbeam and the pivot bearings.

(6) Interferences or binding of the scale platform, stock rack, gates or other ''live'' parts of the scale are common causes of weighing inaccuracy. A weigher should satisfy himself, at the beginning of each weighing period, that all such ''live'' parts have sufficient clearance to prevent interferences.

(g) *General precautions.* (1) The poises of weighbeam scales are carefully adjusted and sealed to a definite weight at the factory and any change in that weight seriously affects weighing accuracy. A weigher, therefore, should be certain that poise parts do not become broken, loose or lost and that no material is added to a poise. Balancing or weighing shall not be performed while a scale ticket is in the slot of a weighbeam poise.

(2) Stops are provided on scale weighbeams to prevent movement of poises back of the zero graduation when balancing or weighing. When the stops become worn or broken and allow a poise to be set behind the zero position, this condition should be reported and corrected without delay.

(3) Foreign objects or loose material in the form of nuts, bolts, washers or other material on any part of the weighbeam assembly, including the counter-balance hanger or counter-balance weights, are potential sources of weighing error. Loose balancing material must be enclosed in the shot cup of the counter-balance hanger, and counter-balance weights must not be of the slotted type which can readily be removed.

(4) Whenever for any reason a weigher has reason to believe that a scale is not functioning properly or not yielding correct weight values, he shall discontinue weighing, report the facts to the parties responsible for scale maintenance, and request inspection, test, or repair of the scale.

(5) When a scale has been adjusted, modified, or repaired in any manner which may affect the accuracy of weighing or weight recording, the weigher shall not use the scale until it has been tested and inspected and found to be accurate.

(6) Count-off men, gate men, or others assigned to open or close scale gates or to drive livestock on or off the scale, shall perform those functions as directed by the weigher's signals or spoken instructions. They shall prevent persons or animals off the scale from being in contact with any part of

the scale platform, stock rack, or gates while the scale is being balanced or used for weighing. They shall not open gates or remove livestock from the scale until directed by the weigher.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 222 and 228 and 15 U.S.C. 46)

[39 FR 40277, Nov. 15, 1974, as amended at 49 FR 39516, Oct. 9, 1984; 61 FR 36282, July 10, 1996; 68 FR 75388, Dec. 31, 2003]

§ 201.76 Reweighing.

Stockyard owners, market agencies, dealers, packers, swine contractors and live poultry dealers must reweigh livestock, livestock carcasses, and live poultry or feed on request of any authorized representative of the Secretary.

[78 FR 51664, Aug. 21, 2013]

§ 201.81 Suspended registrants.

No stockyard owner, packer, market agency, or dealer shall employ any person who has been suspended as a registrant to perform activities in connection with livestock transactions subject to the jurisdiction of the Secretary under the Act during the period of such suspension: *Provided,* That the provisions of this section shall not be construed to prohibit the employment of any person who has been suspended as a registrant until such time as the person demonstrates solvency or obtains the bond required under the Act and regulations. No such person shall be employed, however, until after the expiration of any specified period of suspension contained in the order of suspension.

(7 U.S.C. 222 and 228 and 15 U.S.C. 46)

[49 FR 37374, Sept. 24, 1984]

§ 201.82 Care and promptness in weighing and handling livestock and live poultry.

(a) Each stockyard owner, market agency, dealer, packer, swine contractor and live poultry dealer must exercise reasonable care and promptness with respect to loading, transporting, holding, yarding, feeding, watering, weighing, or otherwise handling livestock, or live poultry to prevent waste of feed, shrinkage, injury, death or other avoidable loss.

(b) Whenever live poultry is obtained under a poultry growing arrangement and the weight of the live poultry is a factor in calculating payment to the grower, the poultry must be transported promptly after loading. The process of obtaining the gross weight must commence immediately upon arrival at the processing plant, holding yard, or other scale normally used for such purpose. The process of obtaining the gross weight which may include, but is not limited to, fueling, uncoupling the trailer, changing the road tractor to a yard tractor or weighing the trailer only, must be conducted without delay; *specifically,* the time period between arrival and completion of the process of obtaining the gross weight must not exceed thirty (30) minutes.

(c) Live poultry dealers must not place poultry from multiple growers on a single live poultry transport trailer or other live poultry transport equipment, creating what is commonly referred to as a ''split load.''

[78 FR 51664, Aug. 21, 2013]

INSPECTION OF BRANDS

§ 201.86 Brand inspection: Application for authorization, registration and filing of schedules, reciprocal arrangements, and maintenance of identity of consignments.

(a) *Application for authorization.* Any department or agency or duly-organized livestock association of any State in which branding or marking of livestock as a means of establishing ownership prevails by custom or statute, which desires to obtain an authorization to charge and collect a fee for the inspection of brands, marks, and other identifying characteristics of livestock, as provided in section 317 of the Act, shall file with the Administrator an application in writing for such authorization. In case two or more applications for authorization to collect a fee for the inspection of brands, marks, and other identifying characteristics of livestock are received from the same State, a hearing will be held to determine which applicant is best qualified.

(b) *Registration and filing of schedules.* Upon the issuance of an authorization to an agency or an association, said agency or association shall register as a market agency in accordance with the provisions of § 201.10, except that no bond need be filed or maintained, and shall file a schedule of its rates and charges for performing the service in the manner and form prescribed by § 201.17.

(c) *Reciprocal arrangements.* Any authorized agency or association may make arrangements with an association or associations in the same or in another State, where branding or marking livestock prevails by custom or statute, to perform inspection service at stockyards on such terms and conditions as may be approved by the Administrator: *Provided,* That such arrangements will tend to further the purpose of the Act and will not result in duplication of charges or services.

(d) *Maintenance of identity of consignments.* All persons having custody at the stockyard of livestock subject to inspection shall preserve the identity of the consignment until inspection has been completed by the authorized inspection agency. Agencies authorized to conduct such inspection shall perform the work as soon after receipt of the livestock as practicable and as rapidly as is reasonably possible in order to prevent delay in marketing, shrinkage in weight, or other avoidable losses.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 203, 204, 207, 217a, 222 and 228)

[49 FR 33005, Aug. 20, 1984, as amended at 68 FR 75388, Dec. 31, 2003]

GENERAL

§ 201.94 Information as to business; furnishing of by packers, swine contractors, live poultry dealers, stockyard owners, market agencies, and dealers.

Each packer, swine contractor, live poultry dealer, stockyard owner, market agency, and dealer, upon proper request, shall give to the Secretary or his duly authorized representatives in writing or otherwise, and under oath or affirmation if requested by such representatives, any information concerning the business of the packer, swine contractor, live poultry dealer, stockyard owner, market agency, or dealer which may be required in order to carry out the provisions of the Act and regulations in this part within such reasonable time as may be specified in the request for such information.

[73 FR 62440, Oct. 21, 2008]

§ 201.95 Inspection of business records and facilities.

Each stockyard owner, market agency, dealer, packer, swine contractor, and live poultry dealer, upon proper request, shall permit authorized representatives of the Secretary to enter its place of business during normal business hours and to examine records pertaining to its business subject to the Act, to make copies thereof and to inspect the facilities of such persons subject to the Act. Reasonable accommodations shall be made available to authorized representatives of the Secretary by the stockyard owner, market agency, dealer, packer, swine contractor, or live poultry dealer for such examination of records and inspection of facilities.

[73 FR 62440, Oct. 21, 2008]

§ 201.96 Unauthorized disclosure of business information prohibited.

No agent or employee of the United States shall, without the consent of the stockyard owner, market agency, dealer, packer, swine contractor, or live poultry dealer concerned, divulge or make known in any manner, any facts or information regarding the business of such person acquired through any examination or inspection of the business or records of the stockyard owner, market agency, dealer, packer, swine contractor, or live poultry dealer, or through any information given by the stockyard owner, market agency, dealer, packer, swine contractor, or live poultry dealer pursuant to the Act and regulations, except to such other agents or employees of the United States as may be required to have such knowledge in the regular course of their official duties or except insofar as they may be directed by the

Administrator or by a court of competent jurisdiction, or except as they may be otherwise required by law.

[73 FR 62440, Oct. 21, 2008]

§ 201.97 Annual reports.

Every packer, live poultry dealer, stockyard owner, market agency, and dealer (except a packer buyer registered to purchase livestock for slaughter only) shall file annually with the Administration a report on prescribed forms not later than April 15 following the calendar year end or, if the records are kept on a fiscal year basis, not later than 90 days after the close of his fiscal year. The Administrator on good cause shown, or on his own motion, may grant a reasonable extension of the filing date or may waive the filing of such reports in particular cases.

(Approved by the Office of Management and Budget under Control Number 0580–0015)

[54 FR 16356, Apr. 24, 1989, as amended at 68 FR 75388, Dec. 31, 2003]

§ 201.98 Packers and dealers not to charge, demand, or collect commission, yardage, or other service charges.

No packer or dealer shall, in connection with the purchase of livestock in commerce, charge, demand, or collect from the seller of the livestock any compensation in the form of commission, yardage, or other service charge unless the charge is for services mandated by law or statute and is not inconsistent with the provisions of the Act.

[61 FR 36282, July 10, 1996]

§ 201.99 Purchase of livestock by packers on a carcass grade, carcass weight, or carcass grade and weight basis.

(a) Each packer purchasing livestock on a carcass grade, carcass weight, or carcass grade and weight basis shall, prior to such purchase, make known to the seller, or to his duly authorized agent, the details of the purchase contract. Such details shall include, when applicable, expected date and place of slaughter, carcass price, condemnation terms, description of the carcass trim, grading to be used, accounting, and any special conditions.

(b) Each packer purchasing livestock on a carcass grade, carcass weight, or carcass grade and weight basis, shall maintain the identity of each seller's livestock and the carcasses therefrom and shall, after determination of the amount of the purchase price, transmit or deliver to the seller, or his duly authorized agent, a true written account of such purchase showing the number, weight, and price of the carcasses of each grade (identifying the grade) and of the ungraded carcasses, an explanation of any condemnations, and any other information affecting final accounting. Packers purchasing livestock on such a basis shall maintain sufficient records to substantiate the settlement of each transaction.

(c) When livestock are purchased by a packer on a carcass weight or carcass grade and weight basis, purchase and settlement therefor shall be on the basis of carcass price. This paragraph does not apply to purchases of livestock by a packer on a guaranteed yield basis.

(d) Settlement and final payment for livestock purchased by a packer on a carcass weight or carcass grade and weight basis shall be on actual hot weights. The hooks, rollers, gambrels or other similar equipment used at a packing establishment in connection with the weighing of carcasses of the same species of livestock shall be uniform in weight. The tare shall include only the weight of such equipment.

(e) Settlement and final payment for livestock purchased by a packer on a USDA carcass grade shall be on an official (final—not preliminary) grade. If settlement and final payment are based upon any grades other than official USDA grades, such other grades shall be set forth in detailed written specifications which shall be made available to the seller or his duly authorized agent. For purposes of settlement and final payment for livestock purchased on a grade or grade and weight basis, carcasses shall be final graded before the close of the second business day

following the day the livestock are slaughtered.

(Approved by the Office of Management and Budget under control number 0580–0015)

(Pub. L. 96–511, 94 Stat. 2812 (44 U.S.C. 3501 *et seq.*); 7 U.S.C. 222 and 228 and 15 U.S.C. 46)

[33 FR 2762, Feb. 9, 1968, as amended at 33 FR 5401, Apr. 5, 1968; 49 FR 37375, Sept. 24, 1984; 54 FR 37094, Sept. 7, 1989; 68 FR 75388, Dec. 31, 2003]

POULTRY—PACKERS AND LIVE POULTRY DEALERS

§ 201.100 Records to be furnished poultry growers and sellers.

(a) *Poultry growing arrangement; timing of disclosure.* As a live poultry dealer who offers a poultry growing arrangement to a poultry grower, you must provide the poultry grower with a true written copy of the offered poultry growing arrangement on the date you provide the poultry grower with poultry house specifications.

(b) *Right to discuss the terms of poultry growing arrangement offer.* As a live poultry dealer, notwithstanding any confidentiality provision in the poultry growing arrangement, you must allow poultry growers to discuss the terms of a poultry growing arrangement offer with:

(1) A Federal or State agency;

(2) The grower's financial advisor or lender;

(3) The grower's legal advisor;

(4) An accounting services representative hired by the grower;

(5) Other growers for the same live poultry dealer; or

(6) A member of the grower's immediate family or a business associate. A business associate is a person not employed by the grower, but with whom the grower has a valid business reason for consulting with when entering into or operating under a poultry growing arrangement.

(c) *Contracts; contents.* Each live poultry dealer that enters into a poultry growing arrangement with a poultry grower shall furnish the grower with a true written copy of the poultry growing arrangement, which shall clearly specify:

(1) The duration of the contract and conditions for the termination of the contract by each of the parties;

(2) All terms relating to the payment to be made to the poultry grower, including among others, where applicable, the following:

(i) The party liable for condemnations, including those resulting from plant errors;

(ii) The method for figuring feed conversion ratios;

(iii) The formula or method used to convert condemnations to live weight;

(iv) The per unit charges for feed and other inputs furnished by each party; and

(v) The factors to be used when grouping or ranking poultry growers; and

(3) Whether a performance improvement plan exists for that grower, and if so specify any performance improvement plan guidelines, including the following:

(i) The factors considered when placing a poultry grower on a performance improvement plan;

(ii) The guidance and support provided to a poultry grower while on a performance improvement plan; and

(iii) The factors considered to determine if and when a poultry grower is removed from the performance improvement plan and placed back in good standing, or when the poultry growing arrangement will be terminated.

(d) *Settlement sheets; contents; supporting documents.* Each live poultry dealer, who acquires poultry pursuant to a contract with a poultry grower, shall prepare a true and accurate settlement sheet (final accounting) and furnish a copy thereof to the poultry grower at the time of settlement. The settlement sheet shall contain all information necessary to compute the payment due the poultry grower. For all such arrangements in which the weight of birds affects payment, the settlement sheet shall show, among other things, the number of live birds marketed, the total weight and the average weight of the birds, and the payment per pound.

(e) *Condemnation and grading certificates.* Each live poultry dealer, who acquires poultry pursuant to a contract with a poultry grower which provides that official U.S. Department of Agriculture condemnations or grades, or

both, are a consideration affecting payment to the grower, shall obtain an official U.S. Department of Agriculture condemnation or grading certificate, or both, for the poultry and furnish a copy thereof to the poultry grower prior to or at the time of settlement.

(f) *Grouping or ranking sheets.* Where the contract between the live poultry dealer and the poultry grower provides for payment to the poultry grower based upon a grouping or ranking of poultry growers delivering poultry during a specified period, the live poultry dealer shall furnish the poultry grower, at the time of settlement, a copy of a grouping or ranking sheet which shows the grower's precise position in the grouping or ranking sheet for that period. The grouping or ranking sheet need not show the names of other growers, but shall show the actual figures upon which the grouping or ranking is based for each grower grouped or ranked during the specified period.

(g) *Live poultry purchases.* Each live poultry dealer who purchases live poultry shall prepare and deliver a purchase invoice to the seller at time of settlement. The purchase invoice shall contain all information necessary to compute payment due the seller. When U.S. Department of Agriculture condemnations or U.S. Department of Agriculture grades, or both, of poultry purchased affect final payment, copies of official U.S. Department of Agriculture condemnation certificates or grading certificates, or both, shall be furnished to the seller at or prior to the time of settlement.

(h) *Written termination notice; furnishing, contents.* (1) A live poultry dealer that ends a poultry growing arrangement with a poultry grower due to a termination, non-renewal, or expiration and subsequent non-replacement of a poultry growing arrangement shall provide the poultry grower with a written termination notice at least 90 days prior to the termination of the poultry growing arrangement. Written notice issued to a poultry grower by a live poultry dealer regarding termination shall contain the following:

(i) The reason(s) for termination;

(ii) When the termination is effective; and

(iii) Appeal rights, if any, that a poultry grower may have with the live poultry dealer.

(2) A live poultry dealer's poultry growing arrangement with a poultry grower shall also provide the poultry grower with the opportunity to terminate its poultry growing arrangement in writing at least 90 days prior to the termination of the poultry growing arrangement.

(Approved by the Office of Management and Budget under control number 0580–0015)

[54 FR 16356, Apr. 24, 1989; 54 FR 18713, May 2, 1989, as amended at 68 FR 75388, Dec. 31, 2003; 74 FR 63277, Dec. 3, 2009]

§ 201.108–1 Instructions for weighing live poultry or feed.

Live poultry dealers who operate scales on which live poultry or feed is weighed for purposes of purchase, sale, acquisition, or settlement are responsible for the accurate weighing of such poultry or feed. They shall supply copies of the instructions in this section to all persons who perform weighing operations for them and direct such persons to familiarize themselves with the instructions and to comply with them at all times. This section shall also apply to any additional weighers who are employed at any time. Weighers must acknowledge their receipt of these instructions and agree to comply with them by signing in duplicate, a form provided by the Packers and Stockyards Programs, Grain Inspection, Packers and Stockyards Administration. One copy of this form is to be filed with a regional office of the Packers and Stockyards Programs, Grain Inspection, Packers and Stockyards Administration and the other copy retained by the Agency employing the weighers. The following instructions shall be applicable to the weighing of live poultry on all scales, except that paragraph (c)(1) of this section is only applicable to the weighing of live poultry on vehicle scales.

(a) *Balancing the empty scale.* (1) The scale must be maintained in zero balance at all times. The empty scale must be balanced each day before weighing begins and thereafter the scale must be balanced; and the zero balance, the time and date the empty

scale was balanced must be mechanically printed on the scale ticket or other basic transaction record before any poultry or feed is weighed. In addition, the zero balance of the scale must be verified whenever a weigher resumes weighing duties after an absence from the scale.

(2) Before balancing the empty scale, the weigher shall notify parties outside the scale house of his/her intention and shall be assured that no persons or vehicles are in contact with the platform. When the empty scale is balanced and ready for weighing, the weigher shall so indicate by appropriate signal.

(3) Weighbeam scales shall be balanced by first seating each poise securely in its zero notch and then moving the balance ball to such position that a correct zero balance is obtained. A scale equipped with a balance indicator is correctly balanced when the indicator comes to rest in the center of the target area. A scale not equipped with a balance indicator is correctly balanced if the weighbeam, when released at the top or bottom of the trig loop, swings freely in the trig loop in such manner that it will come to rest at the center of the trig loop.

(4) Dial scales shall be balanced by releasing all drop weights and operating the balance ball or other balancing device to obtain a correct zero balance. The indicator must visibly indicate zero on the dial reading face and the ticket printer must record a correct zero balance. ''Balance tickets'' shall be filed with other scale tickets issued on that date.

(5) Electronic digital scales should be properly warmed up before use. In most cases it is advisable to leave the electric power on continuously. The zero balance shall be verified by recording the zero balance on a scale ticket. The main indicating element and the remote visual weight display shall indicate zero when the balance is verified. The proper procedure for balancing this type of scale will vary according to the manufacturer. Refer to the operator's manual for specific instructions.

(6) A balance ball or other balancing device shall be operated only when balancing the empty scale and shall not be operated at any time or for any other purpose.

(b) *Sensitivity control.* (1) A scale must be sensitive in response to platform loading if it is to yield accurate weights. It, therefore, is the duty of a weigher to assure himself that interferences, weighbeam friction, or other factors do not impair sensitivity. He shall satisfy himself, at least twice each day, that the scale is sufficiently sensitive, and, if the following requirements are not met, he must report the facts to his superior or employer immediately.

(2) A weighbeam scale with a balance indicator is sufficiently sensitive if, when the scale is balanced with the indicator at the center of the target, movement of the fractional poise one graduation will change the indicator rest point (¼) inch (0.25) or the width of the central target area, whichever is greater.

(3) A weighbeam scale without a balance indicator is sufficiently sensitive if, when the scale is balanced with the weighbeam at the center of the trig loop, movement of the fractional poise two graduations will cause the weighbeam to come to rest at the bottom of the trig loop.

(4) Adjustable damping devices are incorporated in balance indicators and in dial scales to absorb the effects of load impact and to bring the indicator to rest. The weigher must be familiar with the location and adjustment of these damping devices and keep them so adjusted that when the indicator is displaced from a position of rest, it will oscillate freely through at least one complete cycle of movement before coming to rest at its original position.

(5) Friction at weighbeam bearings may reduce the sensitiveness of the scale, cause sluggish weighbeam action and affect weighing accuracy. A weigher must inspect the weighbeam assembly daily to make certain that there is clearance between the weighbeam and the pivot bearings.

(6) Interferences or binding of the scale platform, or other ''live'' parts of the scale, are common causes of weighing inaccuracy. A weigher shall satisfy himself, at the beginning of each weighing period, that all such ''live'' parts have sufficient clearance to prevent interference.

(c) *Weighing the load.* (1) Vehicle scales used to weigh live poultry shall be of sufficient length and capacity to weigh an entire vehicle as a unit; provided, that a trailer may be uncoupled from a tractor and weighed as a single unit. Before weighing a vehicle, either coupled or uncoupled, the weigher shall be assured that the entire vehicle is on the scale platform and that no persons are on the scale platform.

(i) On a weighbeam scale with a balance indicator the weight of a vehicle shall be determined by moving the poises to such positions that the indicator will come to rest within the central target area.

(ii) On a weighbeam scale without a balance indicator the weight shall be determined by moving the poises to such positions that the weighbeam, when released from the top or bottom of the trig loop, will swing freely in the trig loop and come to rest at the approximate center of the trig loop.

(iii) On a dial scale the weight of a vehicle is indicated automatically when the indicator revolves around the dial face and comes to rest.

(iv) On an electronic digital scale the weight of a vehicle is indicated automatically when the weight value indicated is stable.

(v) A feed hopper attached to an electronic digital scale must be empty of feed and the electronic digital scale must be balanced at zero prior to first weighment for each grower or per truckload, whichever is applicable. The date and time that the empty hopper scale is balanced with proof of the zero balance must be mechanically printed on the scale ticket or other permanent record that must be attached to the grower's copy of the scale ticket.

(vi) An onboard weighing system must be level and locked in position and zero balanced prior to weighing. The date and time the onboard scale is balanced with proof of the zero balance must be mechanically printed on the scale ticket or other permanent record that must be attached to the grower's copy of the scale ticket. When more than one grower's feed is weighed, the preceding grower's gross weight can be used for the next grower's tare weight, and can be repeated until the unit is full.

(2) The correct weight is the value in pounds indicated by a weighbeam, dial or digital scale when a stable load balance is obtained. In any case, the weigher should concentrate on the beam tip, balance indicator, dial or digital indicator while weighing and not be concerned with reading the visible weight indications until a stable load balance is obtained. On electronic digital scales, the weigher should concentrate on the pulsing or flickering of weight values to assure that the unit indicates a stable weight before activating the print button.

(d) *Recording the weight.* (1) The gross or tare weight shall be recorded immediately after the load balance is obtained and before any poises are moved or load removed from the scale platform. The weigher shall make certain that the printed weight record agrees with the weight value visibly indicated on the weighbeam, dial or digital indicator when correct load balance is obtained. The weigher shall also assure that the printed weight value is sufficiently distinct and legible.

(2) The weight printing device on a scale shall be operated only to produce a printed or impressed record of the weight while the load is on the scale and correctly balanced. If the weight is not printed clearly and correctly, the ticket shall be marked void and a new one printed before the load is removed from the scale.

(3) When returned feed from a contract poultry grower is picked up and weighed on an onboard weighing system, the weight of the feed must be recorded and a ticket printed. That weight must be used as the tare weight when feed from another contract poultry grower is picked up on the same load. The procedure must be followed each time another grower's feed is added to the load.

(e) *Weigher's responsibilities.* (1) The primary responsibility of a weigher is to determine and record the true weight of live poultry without prejudice or favor to any person or agency and without regard for poultry ownership, price, condition, shrink, or other considerations. A weigher shall not permit the representations or attitudes of any persons or agencies to influence

their judgment or action in performing his/her duties.

(2) Accurate weighing and weight recording require that a weigher shall not permit operations to be hurried to the extent that inaccurate weights or incorrect weight records may result. The gross, tare and net weights must be determined accurately to the nearest minimum graduation. Manual operations connected with balancing, weighing, and recording shall be performed with the care necessary to prevent damage to the accurately machined and adjusted parts of weighbeams, poises, and printing devices. Rough handling of these parts shall be avoided.

(3) Poultry growers, live poultry dealers, sellers, or others having legitimate interest in a load of poultry are entitled to observe the balancing, weighing, and recording procedures. A weigher shall not deny such persons that right or withhold from them any information pertaining to the weight. The weigher shall check the zero balance of the scale or reweigh a load of poultry when requested by such parties or duly authorized representatives of the administrator.

(f) *General precautions.* (1) The poises of weighbeam scales are carefully adjusted and sealed to a definite weight at the factory and any change in that weight seriously affects weighing accuracy. A weigher, therefore, shall observe if poise parts are broken, loose or lost or if material is added to a poise and shall report any such condition to his/her superior or employer. Balancing or weighing shall not be performed while a scale ticket is in the slot of a weighbeam poise.

(2) Stops are provided on scale weighbeams to prevent movement of poises back of the zero graduation when balancing or weighing. When the stops become worn or broken and allow a poise to be set behind the zero position, this condition must be reported by the weigher to their superior or employer and corrected without delay.

(3) Motion detection circuits are a part of electronic scales. They are designed to prevent the printing of weight values if the load has not stabilized within prescribed limits. The weighmaster's duty is to print the actual weight of the load within these limits. This requires printing the actual weight of the load, not one of the other weights that may be within the motion detection limits.

(4) Foreign objects or loose material in the form of nuts, bolts, washers, or other material on any part of the weighbeam assembly, including the counter-balance hanger or counter-balance weights, are potential sources of weighing error. Loose balancing material must be enclosed in the shot cup of the counter-balance hanger and counter-balance weights must not be of the slotted type which can readily be removed.

(5) Whenever, for any reason, a weigher has reason to believe that a scale is not functioning properly or not yielding correct weight values, the weigher shall discontinue weighing, report the facts to the parties responsible for scale maintenance and request inspection, test or repair of the scale.

(6) When a scale has been adjusted, modified, or repaired in any manner which can affect the accuracy of weighing or weight recording, the weigher shall not use the scale until it has been tested and inspected and found to be accurate.

(Approved by the Office of Management and Budget under control number 0580–0015)

[37 FR 4955, Mar. 8, 1972, as amended at 61 FR 36282, July 10, 1996; 68 FR 75388, Dec. 31, 2003; 78 FR 51664, Aug. 21, 2013]

§ 201.200 Sale of livestock to a packer on credit.

(a) No packer whose average annual purchases of livestock exceed $500,000 shall purchase livestock on credit, and no dealer or market agency acting as an agent for such a packer shall purchase livestock on credit, unless: (1) Before purchasing such livestock the packer obtains from the seller a written acknowledgment as follows:

On this date I am entering into a written agreement for the sale of livestock on credit to _____, a packer, and I understand that in doing so I will have no rights under the trust provisions of section 206 of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 196, Pub. L. 94–410), with respect to any such credit sale. The written agreement for such selling on credit

Covers a single sale.

Provides that it will remain in effect until (date).
Provides that it will remain in effect until canceled in writing by either party.
(Omit the provisions not applicable.)
Date
Signature

(2) Such packer retains such acknowledgment, together with all other documents, if any, setting forth the terms of such credit sales on which the purchaser and seller have agreed, and such dealer or market agency retains a copy thereof, in his records for such time as is required by any law, or by written notice served on such person by the Administrator, but not less than two calendar years from the date of expiration of the written agreement referred to in such acknowledgment; and

(3) Such seller receives a copy of such acknowledgment.

(b) Purchasing livestock for which payment is to be made by a draft which is not a check, shall constitute purchasing such livestock on credit within the meaning of paragraph (a) of this section. (See also §201.43(b)(1).)

(c) The provisions of this section shall not be construed to permit any transaction prohibited by §201.61(a) relating to financing by market agencies selling on a commission basis.

(Approved by the Office of Management and Budget under control number 0580–0015)

(Sec. 401, 42 Stat. 168 (7 U.S.C. 221); sec. 409, as added by sec. 7, 90 Stat. 1250 (7 U.S.C 228b); 7 CFR 2.17, 2.54; 42 FR 35625; Pub. L. 96–511, 94 Stat. 2812 (44 U.S.C. 3501 *et seq.*); 7 U.S.C. 222 and 228 and 15 U.S.C. 46)

[42 FR 49929, Sept. 8, 1977, as amended at 49 FR 39516, Oct. 9, 1984; 54 FR 37094, Sept. 7, 1989; 68 FR 75388, Dec. 31, 2003]

§§ 201.213–201.214 [Reserved]

§ 201.215 Suspension of delivery of birds.

The Secretary may consider various criteria when determining whether or not reasonable notice has been given by a live poultry dealer to a poultry grower for suspension of delivery of birds. These criteria include, but are not limited to:

(a) Whether the written notice adequately states the reason for the suspension of delivery, the length of the suspension of delivery, and the anticipated date the delivery of birds will resume; and

(b) Whether a catastrophic or natural disaster, or other emergency, such as an unforeseen bankruptcy, has occurred that has prevented a live poultry dealer from providing reasonable notice.

[76 FR 76889, Dec. 9, 2011, as amended at 80 FR 6430, Feb. 5, 2015]

§ 201.216 Additional capital investments criteria.

The Secretary may consider various criteria in determining whether a requirement that a poultry grower or swine production contract grower make additional capital investments over the life of a production contract or growing arrangement constitutes a violation of the Act. These criteria include, but are not limited to:

(a) Whether a packer, swine contractor or live poultry dealer failed to give a poultry grower or swine production contract grower discretion to decide against the additional capital investment requirement;

(b) Whether the additional capital investment is the result of coercion, retaliation or threats of coercion or retaliation by the packer, swine contractor or live poultry dealer;

(c) Whether the packer, swine contractor or live poultry dealer intends or does substantially reduce or end operations at the slaughter plant or processing facility or intends or does substantially reduce or end production operations within 12 months of requiring the additional capital investment, absent the occurrence of a catastrophic or natural disaster, or other emergency, such as unforeseen bankruptcy;

(d) Whether the packer, swine contractor, or live poultry dealer required some poultry growers or swine production contract growers to make additional capital investments, but did not require other similarly situated poultry growers or swine production contract growers to make the same additional capital investments;

(e) The age and number of recent upgrades to, or capital investments in, the poultry grower's or swine production contract grower's operations;

(f) Whether the cost of the required additional capital investments can reasonably be expected to be recouped by the poultry grower or swine production contract grower;

(g) Whether a reasonable time period to implement the required additional capital investments is provided to the poultry grower or swine production contract grower; and

(h) Whether equipment changes are required with respect to equipment previously approved and accepted by the packer, swine contractor, or live poultry dealer, if existing equipment is functioning as it was intended to function unless the packer, swine contractor, or live poultry dealer provides adequate compensation incentives to the poultry grower or swine production contract grower.

[76 FR 76889, Dec. 9, 2011]

§ 201.217 Reasonable period of time to remedy a breach of contract.

The Secretary may consider various criteria when determining whether a packer, swine contractor or live poultry dealer has provided a poultry grower or swine production contract grower a reasonable period of time to remedy a breach of contract that could lead to contract termination. These criteria do not limit a packer, swine contractor or live poultry dealer's rights under a contract or agreement where food safety or animal welfare is concerned. These criteria, include, but are not limited to:

(a) Whether the packer, swine contractor or live poultry dealer provided written notice of the breach of contract to the poultry grower or swine production contract grower upon initial discovery of that breach of contract if the packer, swine contractor or live poultry dealer intends to take an adverse action, including termination of a contract, against the poultry grower or swine production contract grower based on that breach of contract by the poultry grower or swine production contract grower;

(b) Whether the notice in paragraph (a) of this section includes the following:

(1) A description of the act or omission believed to constitute a breach of contract, including identification of the section of the contract believed to have been breached;

(2) The date of the breach;

(3) The means by which the poultry grower or swine production contract grower can satisfactorily remedy the breach, if possible, based on the nature of the breach; and

(4) A date that provides a reasonable time, based on the nature of the breach, by which the breach must be remedied.

(c) Whether the packer, swine contractor or live poultry dealer took into account the poultry grower's or swine production contract grower's ongoing responsibilities related to the raising and handling of the poultry or swine under their care when establishing the date by which a breach should be remedied; and

(d) Whether the poultry grower or swine production contract grower was afforded adequate time from the date of the notice of the alleged breach to rebut the allegation of a breach.

[76 FR 76889, Dec. 9, 2011]

§ 201.218 Arbitration.

(a) In any livestock or poultry production contract that requires the use of arbitration the following language must appear on the signature page of the contract in bold conspicuous print: ''*Right to Decline Arbitration*. A poultry grower, livestock producer or swine production contract grower has the right to decline to be bound by the arbitration provisions set forth in this agreement. A poultry grower, livestock producer or swine production contract grower shall indicate whether or not it desires to be bound by the arbitration provisions by signing one of the following statements; failure to choose an option will be treated as if the poultry grower, livestock producer or swine production contract grower declined to be bound by the arbitration provisions set forth in this Agreement:

I decline to be bound by the arbitration provisions set forth in this Agreement _____

I accept the arbitration provisions as set forth in this Agreement _____''

(b) The Secretary may consider various criteria when determining whether the arbitration process provided in a

production contract provides a meaningful opportunity for the poultry grower, livestock producer, or swine production contract grower to participate fully in the arbitration process. These criteria include, but are not limited to:

(1) Whether the contract discloses sufficient information in bold, conspicuous print describing all the costs of arbitration to be paid by the poultry grower, swine production contract grower, or livestock producer, and the arbitration process and any limitations on legal rights and remedies in such a manner as to allow the poultry grower, livestock producer or swine contract production grower to make an informed decision on whether to elect arbitration for dispute resolution;

(2) Whether provisions in the entire arbitration process governing the costs and time limits are reasonable;

(3) Whether the poultry grower, livestock producer, or swine production contract grower is provided access to and opportunity to engage in reasonable discovery of information held by the packer, swine contractor or live poultry dealer;

(4) Whether arbitration is required to be used to resolve only disputes relevant to the contractual obligations of the parties; and

(5) Whether a reasoned, written opinion based on applicable law, legal principles and precedent for the award is required to be provided to the parties.

[76 FR 76889, Dec. 9, 2011]

PART 202—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE PACKERS AND STOCKYARDS ACT

RULES OF PRACTICE APPLICABLE TO RATE PROCEEDINGS

Sec.

RULES OF PRACTICE APPLICABLE TO REPARATION PROCEEDINGS

RULES OF PRACTICE APPLICABLE TO ALL OTHER PROCEEDINGS

AUTHORITY: 7 U.S.C. 228(a); 7 CFR 2.22 and 2.81.

SOURCE: 43 FR 30510, July 14, 1978, unless otherwise noted.

RULES OF PRACTICE APPLICABLE TO RATE PROCEEDINGS

SOURCE: Sections 202.1 through 202.7 appear at 53 FR 51236, Dec. 21, 1988, unless otherwise noted.

§ 202.1 Applicability of other rules.

The Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, 7 CFR part 1, subpart H, are applicable to all rate proceedings under Sections 304, 305, 306, 307 and 310 of the Packers and Stockyards Act, 1921, as amended, 7 U.S.C. 205, 206, 207, 208 and 211, except insofar as those Rules are in conflict with any provision herein.

§ 202.2 Definitions.

As used in these rules:

(a) *Rate proceeding* means a proceeding involving the determination and prescription of any rate or charge made or proposed to be made for any stockyard service furnished at a stockyard by a stockyard owner or market agency, or a proceeding involving any rule, regulation or practice affecting any such rate or charge; and

(b) *Administrator* means the Administrator of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) (GIPSA), or any officer or employee of GIPSA to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act for the Administrator.

§ 202.3 Institution of proceedings.

(a) *Informal complaint.* Any interested person desiring to complain of the lawfulness of any rate or charge made or proposed to be made for any stockyard service furnished at a stockyard by a stockyard owner or market agency, or rule, regulation or practice affecting any such rate or charge, may file an informal complaint with the Administrator.

(b) *Investigation.* If there appears to be any reasonable ground for doing so, the Administrator will investigate the matter complained of. If the Administrator reasonably believes that there are not sufficient facts to form the basis for further proceeding, the matter may be dropped. If it is dropped, the person filing the informal complaint will be informed.

(c) *Status of person filing.* A person filing an informal complaint will be a party to a rate proceeding if the Administrator files such person's informal complaint as a formal complaint, or if the Judge permits such person to intervene upon written application.

(d) *Formal complaint.* A rate proceeding may be instituted only upon filing of a formal complaint by the Administrator. A formal complaint may be filed on the initiative of the Administrator, or on the basis of an informal complaint, or by filing the informal complaint as a formal complaint. A formal complaint filed by the Administrator, or a summary thereof, will be published in the FEDERAL REGISTER, together with notice of the time by which, and the place where, any interested person may file a written request to be heard.

§ 202.4 Answer and reply.

Respondent is not required to file an answer. If an answer is filed, complainant is not required to file a reply.

§ 202.5 Hearing.

The hearing will be oral unless all parties waive oral hearing. It will be written if not oral. Notice of the date, time and place of oral hearing, or of the date and place for filing of written submissions in a written hearing, will be served on the Administrator and the respondent, and on such other persons as have requested in writing to be heard.

§ 202.6 Taking no position on the merits.

The proceeding may be instituted by filing of the informal complaint as a formal complaint, and the Administrator may take no position on the merits of the case.

§ 202.7 Modification or vacation of final order.

(a) *Informal petition.* Any interested person may file an informal petition to modify or vacate a final order at any time. Any such petition must be filed with the Administrator, be based on matters arising after the issuance of the final order, and set forth such matters, and the reasons or conditions relied on, with such particularity as is practicable. Any such informal petition will be handled as otherwise provided for an informal complaint.

(b) *Formal motion.* A final order may be modified or vacated at any time only upon filing of a formal motion by the Administrator. Such a motion may be filed on the initiative of the Administrator, on the basis of an informal petition, or by filing of an informal petition as a formal motion.

(c) *Publication.* If the modification or vacation sought would involve an increase of a rate or charge lawfully prescribed by the Secretary, or involve a rate or charge in addition to what is specified in the final order, or involve a regulation or practice so affecting such a rate or charge, the formal motion, or

a summary thereof, will be published in the FEDERAL REGISTER, together with notice of the place, and the time by which, any interested person may file a written request to be heard.

(d) *Proceedings.* Proceedings upon such a formal motion will be as otherwise provided for a formal complaint.

RULES OF PRACTICE APPLICABLE TO REPARATION PROCEEDINGS

§ 202.101 Rule 1: Meaning of words.

In these rules, words in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 202.102 Rule 2: Definitions.

Terms defined in the Act shall mean the same in these rules as in the Act. In addition, and except as may be provided otherwise in these rules:

Act means the Packers and Stockyards Act, 1921, and legislation supplementary thereto and amendatory thereof, 7 U.S.C. 181 *et seq.;*

Agency means those divisions and offices of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) of the Department which are charged with administration of the Act;

Agency Head means the Administrator, Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) of the Department, or any officer or employee of the Agency to whom authority is lawfully delegated to act for the Administrator;

Complainant means the party who files a complaint and claims reparation, or on whose behalf a complaint is filed and reparation is claimed, in a reparation proceeding;

Department means the United States Department of Agriculture;

Docketing of a reparation proceeding means transmittal of papers to the Hearing Clerk and assignment of a docket number as provided in Rule 8, § 202.108, of these rules;

Hearing means that part of a reparation proceeding which involves the submission of evidence for the record and means either an oral or a written hearing;

Hearing Clerk means the Hearing Clerk of the Department (see 7 CFR 2.25(a)(3));

Judicial Officer means the official of the Department delegated authority by the Secretary, pursuant to the Act of April 4, 1940 (7 U.S.C. 450c–450g) and Reorganization Plan No. 2 of 1953, to perform the function involved (see 7 CFR 2.35);

Mail means to deposit an item in the United States mail with postage affixed and addressed as necessary to cause it to be delivered to the address shown by ordinary mail, or by certified or registered mail if specified.

Presiding Officer means any attorney who is employed in the Office of the General Counsel of the Department and is assigned so to act in a reparation proceeding;

Re-mail means to mail by ordinary mail to an address an item that has been returned after being sent to the same address by certified or registered mail.

Reparation proceeding or *Proceeding* means a proceeding under the Act before the Secretary, in which an order for the payment of money is claimed and in which the Secretary is not a party of record;

Report means the report to the Judicial Officer of the presiding officer's recommended findings of fact and conclusions with respect to all material issues of fact, law or discretion, as well as the reasons or basis therefor, and order, in a reparation proceeding.

Respondent means the party against whom a complaint is filed and reparation is claimed, in a reparation proceeding;

Secretary means the Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority is lawfully delegated to act for the Secretary;

[43 FR 30510, July 14, 1978, as amended at 46 FR 60414, Dec. 10, 1981; 55 FR 41183, Oct. 10, 1990; 60 FR 8465, Feb. 14, 1995]

§ 202.103 Rule 3: Beginning a reparation proceeding.

(a) *Filing.* A reparation proceeding is begun by filing a complaint. Any interested person (including any agency of a state or territory having jurisdiction over persons subject to the Act in such

state or territory) desiring to complain of anything done or omitted to be done by any stockyard owner, market agency, or dealer in violation of sections 304, 305, 306, or 307, or of an order of the Secretary made under title III, of the Act, may file a complaint to begin a reparation proceeding.

(b) *Form.* The complaint must be in writing, state the facts of the matter complained of, identify each person complained against (respondent), and identify each person who complains against such respondent and claims reparation from such respondent. It may be on a printed form supplied by the Agency, or may be a formal document, or may be a letter, mailgram, or telegram. It may be typewritten or handwritten. If it is not on a printed form supplied by the Agency, the Agency Head may, prior to docketing of the proceeding, recommend to the complainant that an amended complaint be filed on such a printed form.

(c) *Contents and attachments.* So far as practicable, the complaint should include the following items as applicable:

(1) Date and place where the alleged violation occurred;

(2) Quantity and quality of the livestock involved;

(3) Whether a sale is involved and, if so, the date, sale price, and amount actually paid and received;

(4) Whether a consignment is involved and, if so the date, reported proceeds, gross, net;

(5) Amount of reparation claimed, and method of computation;

(6) Name and address of each partner or member, if a partnership or joint venture is involved;

(7) Name and address of each person involved, including any agent representing the complainant or the respondent in the transaction involved;

(8) Other material facts, including terms of contract; and

(9) True copies of all available papers relating to the transaction complained about, including shipping documents, letters, telegrams, invoices, manifests, accounts of sales, and special contracts or agreements, and checks and drafts. If it appears that any such item has been omitted from the complaint, the Agency Head may, prior to docketing of the proceeding, recommend to the complainant that such item be supplied by written amendment to the complaint.

(d) *Where to file.* The complaint should be transmitted or delivered to any area office of the Agency, or to the headquarters of the Agency in Washington, DC, or delivered to any full time employee of the Agency.

(e) *Time for filing.* The complaint must be received by the Department within 90 days after accrual of the cause of action alleged in it. If a complaint is transmitted or delivered to an office of the Department, it shall be deemed to be received by the Department when it reaches such office. If a complaint is delivered to a full time employee of the Agency, it shall be deemed to be received by the Department when it is received by such employee.

(f) *Amendment.* The complaint may be amended at any time prior to the close of an oral hearing or the filing of the last evidence in a written hearing, except that:

(1) An amendment cannot add a respondent if it is filed more than 90 days after accrual of the cause of action against such respondent;

(2) An amendment cannot state a new and different cause of action if it is filed more than 90 days after accrual of such new and different cause of action; and

(3) After the first amendment, or after the filing of an answer by the respondent, an amendment may not be filed without the written consent of the respondent, or leave of the presiding officer, or, prior to docketing of the proceeding, leave of the Agency Head. Any such amendment must be filed in writing and signed by the complainant or the attorney or representative of the complainant. If any such amendment is filed before the initial service of the complaint on the respondent, it shall be served on the respondent only if the complaint is served as provided in Rule 4(b), § 202.104(b). If any such amendment is filed after such service, it shall be served on the respondent in any case.

(g) *Withdrawal.* At any time, a complainant may withdraw a complaint

filed by or on behalf of the same complainant, thus terminating the reparation proceeding on such complaint unless a counterclaim or another complaint is pending therein. If a complainant fails to cooperate with the Secretary in the disposition of the matter complained of, such complainant may be presumed to desire to withdraw the complaint filed by or on behalf of such complainant, after service on the parties of written notice of the facts of such failure and reasonable opportunity for such complainant to state whether such presumption is correct.

[43 FR 30510, July 14, 1978, as amended at 60 FR 8465, Feb. 14, 1995]

§ 202.104 Rule 4: Agency action.

(a) *Informal disposition.* If there appears to be any reasonable ground for doing so, the Agency Head shall investigate the matter complained of. If the Agency Head reasonably believes that there are not sufficient facts to form the basis for further proceeding, the matter may be dropped, without prejudice to subsequent court action on the same cause of action; if it is dropped, the person filing the complaint shall be informed. If the statements in the complaint, and information obtained in the investigation, seem to warrant such action, the Agency Head may make an effort to obtain the consent of the parties to an amicable or informal adjustment of the matter by communication with the parties or their attorneys or representatives. Such communication may be written or oral or both.

(b) *Service of complaint.* If the matter is not disposed of as provided in paragraph (a), the complaint, together with any amendment which has been filed, shall be served on the respondent with a notice that an answer is required.

(c) *Service of report of investigation.* A report prepared by the Agency, of its investigation of the matter complained of, and supplements to such a report, may be served on the parties and made a part of the record of the proceeding. Whether such a report or supplement shall be prepared, and whether it shall be served on the parties and made a part of the record, and its contents, shall be in the discretion of the Agency Head. The Judicial Officer shall consider information in such a report or supplement as part of the evidence in the proceeding, to the extent that such information is relevant and material to the proceeding. Any party may submit evidence in rebuttal of such information as is provided generally in these rules for the submission of evidence. Oral testimony, to the extent credible, shall be given greater weight as evidence than such information.

§ 202.105 Rule 5: Filing; time for filing; service.

(a) *Filing; number of copies.* Prior to docketing of a proceeding under these rules, all documents and papers other than the initial complaint, filed in the proceeding, shall be filed with the Agency. After such docketing of a proceeding, all such documents and papers shall be filed with the hearing clerk, *Provided,* That all such documents and papers, except a petition for disqualification of a presiding officer, shall be filed with the presiding officer if the parties have been served with written notice to do so. Each such document or paper shall be filed in quadruplicate with an extra copy for each party in excess of two, except as otherwise provided in these rules. Any document or paper not filed in the required number of copies, except an initial complaint, may be returned to the party filing it.

(b) *Effective date of filing.* Any document or paper other than an initial complaint, filed in a proceeding under these rules, shall be deemed to be filed at the time when it reaches the headquarters of the Department in Washington DC, or, if authorized to be filed with an officer or employee of the Department at any place outside the District of Columbia, it shall be deemed to be filed at the time when it reaches the office of such officer or employee.

(c) *Additional time for filing.* The time for the filing of any document or paper other than an initial complaint, in a proceeding under these rules, may upon request be extended as reasonable, by the agency head prior to docketing of the proceeding, or by the presiding officer, or by the judicial officer; notice of any extension of time shall be served on all parties. After docketing of the proceeding, in all instances in which time permits, notice of a request for

extension of time shall be given to parties other than the one filing such request, with opportunity to submit views concerning the request.

(d) *Computation of time.* Saturdays, Sundays, and Federal holidays shall be included in computing the time allowed for the filing of any document or paper: *Provided,* That, when such time expires on a Saturday, Sunday, or Federal holiday, such time shall be extended to include the next following business day.

(e) *Who shall make service.* Copies of all documents or papers required or authorized by the rules in this part to be filed with the Agency shall be served on the parties by the Agency, and copies of all documents or papers required or authorized by the rules in this part to be filed with the Hearing Clerk shall be served on the parties by the Hearing Clerk, unless any such document or paper is served by some other employee of the Department, or by a U.S. marshal or deputy marshal, or as otherwise provided herein, or as otherwise directed by the presiding officer or Judicial Officer.

(f) *Service on party.* (1) Any complaint or other document initially served on a person to make that person a party respondent in a proceeding, a final order, or other document specifically ordered by the presiding officer or Judicial Officer to be served by certified or registered mail, shall be deemed to be received by any party to a proceeding on the date of delivery by certified or registered mail to the last known principal place of business of such party, last known principal place of business of the attorney or representative of record of such party, or last known residence of such party if an individual, *provided that,* if any such document or paper is sent by certified on registered mail but is returned marked by the postal service as unclaimed or refused, it shall be deemed to be received by such party on the date of remailing by ordinary mail to the same address.

(2) Any document or paper, other than one specified in paragraph (f)(1) of this section or written questions for a deposition as provided in § 202.109(c)(3), shall be deemed to be received by any party to a proceeding on the date of mailing by ordinary mail to the last known principal place of business of such party, last known principal place of business of the attorney or representative or record of such party, or last known residence of such party if an individual.

(3) Any document or paper served other than by mail on any party to a proceeding shall be deemed to be received by such party on the date of:

(i) Delivery to any responsible individual at, or leaving in a conspicuous place at, the last known principal place of business of such party, last known principal place of business of the attorney or representative of record of such party, or last known residence of such party if an individual, or

(ii) Delivery to such party if an individual, to an officer or director of such party if a corporation, or to a member of such party if a partnership, at any location.

(g) *Service on another.* Any subpoena or other document or paper served on any person other than a party to a proceeding shall be deemed to be received by such person on the date of:

(1) Delivery by certified mail or registered mail to the last known principal place of business of such person, last known principal place of business of the attorney or representative of record of such person, or last known residence of such person if an individual;

(2) Delivery other than by mail to any responsible individual at, or leaving in a conspicuous place at, any such location; or

(3) Delivery to such party if an individual, to an officer or director of such party if a partnership, at any location.

(h) *Proof of service.* Any of the following, in the possession of the Department, showing such service, shall be deemed to be accurate:

(1) A certified or registered mail receipt returned by the postal service with a signature;

(2) An official record of the postal service;

(3) An entry on a docket record or a copy placed in a docket file by the Hearing Clerk of the Department or by an employee of the Hearing Clerk in the ordinary course of business;

(4) A certificate of service, which need not be separate from and may be

incorporated in the document or paper of which it certifies service, showing the method, place and date of service in writing and signed by an individual with personal knowledge thereof, *Provided* that such certificate must be verified by oath or declaration under penalty of perjury if the individual certifying service is not a party to the proceeding in which such document or paper is served, an attorney or representative of record for such a party, or an official or employee of the United States or of a State of political subdivision thereof.

[43 FR 30510, July 14, 1978, as amended at 55 FR 41183, Oct. 10, 1990; 60 FR 8465, Feb. 14, 1995]

§ 202.106 Rule 6: Answer.

(a) *Filing and service.* Within 20 days after service on a respondent, of a complaint or amendment of a complaint, such person shall file an answer in writing, signed by such person or by the attorney or representative of such person. If a respondent desires an oral hearing, a request for it should be included with the answer of such person. If any answer or amended answer is filed, it shall be served on the complainant.

(b) *Required contents.* If a respondent desires to make a defense, the answer of such person shall contain a precise statement of the facts which constitute the grounds of defense, and shall specifically admit, deny, or explain each of the allegations of the complaint, except that, if the respondent is without knowledge, such answer shall state that. If a respondent does not desire to make a defense, the answer of such person shall contain an admission of all the allegations of the complaint, or an admission of liability to the complainant in the full amount claimed by the complainant as reparation, or both. An answer may be stricken for failure to comply with these requirements; notice of an order so striking an answer shall be served on the parties; within 20 days after service on a respondent of such a notice, such person shall file an answer which complies with these requirements.

(c) *Setoff, counterclaim or cross-claim.* The answer may assert a setoff, counterclaim, or cross-claim, or any combination thereof. No counterclaim or cross-claim shall be considered unless it is based on a violation for which the act authorizes reparation to be ordered to be paid, and filed within 90 days after accrual of the cause of action alleged therein: *Provided*, That a counterclaim not filed within such time limit may be considered if based on a transaction complained of in the complaint. Any cross-claim asserted against a corespondent, based on a violation for which the act authorizes reparation to be ordered to be paid, and filed within 90 days after accrual of the cause of action alleged therein, shall be served on such person as a complaint; within 20 days after such service, such person shall file an answer thereto in compliance with the above requirements for an answer to a complaint.

(d) *Failure to file.* If a respondent fails to file an answer as required above, such persons shall be deemed to have admitted all the allegations of the complaint or cross-claim against such person, and to have consented to the issuance of a final order in the proceeding, based on all evidence in the record. For this purpose, the evidence in the record may include information contained in a report of investigation made a part of the record pursuant to rule 4(c), § 202.104(c), and evidence received in a hearing, oral or written, held subsequent to the expiration of the time for filing such answer, but shall not be limited to such information and evidence. Such a respondent shall not be entitled to service provided in these rules, of any notice or document except the final order in the proceeding.

§ 202.107 Rule 7: Reply.

(a) *Filing and service.* If the answer asserts a counterclaim or a setoff, the complainant may file a reply in writing within 20 days after service of the answer on such person. If any reply or amended reply is filed, it shall be served on the respondent.

(b) *Contents.* The reply shall be confined strictly to the matters alleged in the counterclaim or setoff asserted in the answer. It shall contain a precise statement of the facts which constitute the grounds of defense to the counterclaim or setoff and shall specifically

admit, deny, or explain each of the allegations of the answer constituting such counterclaim or setoff, except that, if the complainant is without knowledge, the reply shall state that.

(c) *Failure to file.* If no reply is filed, the allegations of the answer shall be regarded as denied.

[43 FR 30510, July 14, 1978, as amended at 55 FR 41184, Oct. 10, 1990]

§ 202.108 Rule 8: Docketing of proceeding.

Promptly following receipt of the answer, or the reply (if the answer asserts a counterclaim or a setoff), or following the expiration of the period of time prescribed above for the filing of the answer or of the reply, the agency head shall transmit all of the papers which have been filed in the proceeding (including the investigation report if any has been served on the parties) to the hearing clerk, who shall assign a docket number to the proceeding. Thereafter the proceeding shall be referred to by such number. The hearing clerk shall promptly transmit all such papers to the Office of the General Counsel for assignment of a presiding officer.

§ 202.109 Rule 9: Depositions.

(a) *Application.* Any party may file an application for an order for the taking of testimony by deposition, at any time after docketing of a proceeding and before the close of an oral hearing or the filing of such party's evidence in a written hearing therein. The application shall set forth: (1) The name and address of the proposed deponent; (2) the name and address of the person (referred to in this section as the ''officer'') before whom the proposed examination is to be made; (3) the reasons why such deposition should be taken, which must show that it may be able to be used as set forth in paragraph (i) of this section; (4) whether the proposed examination is to be on interrogatories or oral; and (5) if oral, a suggested time and place where the proposed deposition is to be made and a suggested manner in which the proposed deposition is to be conducted (telephone, audio-visual telecommunication, or by personal attendance of the individuals who are expected to participate in the deposition). The application for an order for the taking of testimony by deposition shall be made in writing, unless it is made orally on the record at an oral hearing.

(b) *Response; service.* If any such application is made orally on the record at an oral hearing, each party other than the applicant, present at such hearing, may respond to it orally. If any such application is in writing it shall be served on each party other than the applicant, and each such other party shall have not less than 20 days, from the date of service on such party of the application, to file a written response to it.

(c) *Written questions (interrogatories).* (1) If the examination will be oral, parties who will not be present or represented at it may file written questions with the officer prior to the time of the examination.

(2) The presiding officer may direct, or the parties may agree, that the deposition, if taken, shall be taken by means of written questions. If the presiding officer finds, upon the protest of a party to the proceeding, that such party has a principal place of business or residence more than 100 miles from the place of the examination and that it would constitute an undue hardship on such party to be present or represented at an oral examination at such place, the deposition, if taken, shall be taken by means of written questions. In any such case, the presiding officer shall state on the record at the oral hearing that, or shall serve the parties with notice that, the deposition, if taken, shall be taken by means of written questions.

(3) If the examination is conducted by means of written questions, copies of the applicant's questions must be received by the other party to the proceeding and the officer at least 10 days prior to the date set for the examination unless otherwise agreed, and any cross questions of a party other than the applicant must be received by the applicant and the officer at any time prior to the time of the examination.

(d) *Order.* (1) The presiding officer, if satisfied that good cause for taking the deposition is present, may order the taking of the deposition.

(2) The order shall be served on the parties and shall include:

(i) The name and address of the officer before whom the deposition is to be made;

(ii) The name of the deponent;

(iii) Whether the deposition will be oral or on written questions;

(iv) If the deposition is oral, the manner in which the deposition is to be conducted (telephone, audio-visual telecommunication, or personal attendance of those who are to participate in the deposition); and

(v) The time, which shall not be less than 20 days after the issuance of the order, and place.

(3) The officer, time, place, and manner of the deposition as stated in the presiding officer's order need not be the same as the officer, time, place, and manner suggested in the application.

(4) The deposition shall be conducted in the manner (telephone, audio-visual telecommunication, or personal attendance of those who are to participate in the deposition) agreed to by the parties.

(5) If the parties cannot agree on the manner in which the deposition is to be conducted:

(i) The deposition shall be conducted by telephone unless the presiding officer determines that conducting the deposition by audio-visual telecommunication:

(A) Is necessary to prevent prejudice to a party;

(B) Is necessary because of a disability of any individual expected to participate in the deposition; or

(C) Would cost less than conducting the deposition by telephone.

(ii) If the deposition is not conducted by telephone, the deposition shall be conducted by audio-visual telecommunication unless the presiding officer determines that conducting the deposition by personal attendance of any individual who is expected to participate in the deposition:

(A) Is necessary to prevent prejudice to a party;

(B) Is necessary because of a disability of any individual expected to participate in the deposition; or

(C) Would cost less than conducting the deposition by telephone or audio-visual telecommunication.

(e) *Qualifications of officer.* No deposition shall be made except before an officer authorized by the law of the United States or by the law of the place of the examination to administer oaths, or before an officer authorized by the Secretary to administer oaths, or before the presiding officer. No deposition shall be made before an officer who is a relative (within the third degree by blood or marriage), employee, attorney, or representative of any party (or an employee of an attorney or representative of any party), or who is financially interested in the result of the proceeding.

(f) *Procedure on examination.* The deponent shall be examined under oath or affirmation, and the testimony of the deponent shall be recorded by the officer, or by some person under the direction and in the presence of the officer. If the examination is on interrogatories, they shall be propounded by the officer. If the examination is oral, the deponent shall be examined first by the party at whose instance the deposition is taken, or the representative of such party, and shall be subject to cross-examination by any other party or the representative thereof who is present at the examination; the officer shall propound any interrogatories filed with the officer by parties not present or represented at the examination.

(g) *Certification and filing by officer.* The officer shall certify on the transcript or recording that the deponent was duly sworn by the officer and that the transcript or recording is a true record of the deponent's testimony, with such exceptions as the certificate shall specify. The officer shall then securely seal the transcript or recording, together with three copies of the transcript or recording, with an extra copy for each party in excess of two, in an envelope, and mail the same by registered or certified mail to the presiding officer.

(h) *Service; correction.* After the transcript or recording is received by the presiding officer, it shall promptly be served on all parties. Any party, within 20 days after such service, may file a written motion proposing corrections to the transcript or recording. Any such motion shall be served on each

party other than the one filing it, who shall have 10 days to file a written response to it. Any such response shall be served on each party other than the one filing it. Such documents, if filed, shall be a part of the record of the proceeding if any portion of the transcript or recording is made a part of the record. All portions of the transcript or recording which are not referred to in any such motion shall be presumed to be accurate except for obvious typographical errors.

(i) *Use.* If a written hearing is held, a transcript or recording, of a deposition ordered and taken in accord with this section, may be made a part of the record as evidence by any party, by written motion filed with such party's evidence. If an oral hearing is held, except as otherwise provided in these rules, such a transcript or recording may be made a part of the record as evidence, on written motion filed by any party, or oral motion of any party made at the oral hearing, if no party objects after reasonable notice and opportunity to do so, or if the presiding officer finds that the evidence is otherwise admissible and:

(1) That the witness is dead;

(2) That the witness is unable to attend or testify for any good reason including age, sickness, infirmity, or imprisonment;

(3) That the party offering the transcript or recording has tried without success to procure the attendance of the witness by subpoena; or

(4) That such exceptional circumstances exist as to make it desirable, in the interests of justice and with due regard to the importance of presenting the testimony orally before the presiding officer, to allow the transcript or recording to be used.

If any portion of a transcript or recording of a deposition is made a part of the record as evidence on motion of any party, any other party may make a part of the record as evidence the remainder, or any other portion, of the transcript or recording.

(j) *Expenses.* Fees and reimbursements payable to an officer taking a deposition, or other person recording the testimony in the deposition, shall be paid by the party at whose instance the deposition is taken.

(k) *Subpoenas.* No subpoena can issue, to compel attendance, testimony, or production of documentary evidence, at an examination under this rule 9.

(l) *Agreement of parties.* In any case, any transcript or recording of any deposition, or any part of such a transcript or recording, may be made a part of the record as evidence by agreement of the parties other than a party failing to file an answer as required in these rules.

[43 FR 30510, July 14, 1978, as amended at 55 FR 41184, Oct. 10, 1990; 60 FR 8465, Feb. 14, 1995]

§ 202.110 Rule 10: Prehearing conference.

(a) The presiding officer, at any time prior to the commencement of the hearing, may request the parties or their counsel to appear at a conference before the presiding officer to consider:

(1) The simplification of issues;

(2) The necessity of amendments to pleadings;

(3) The possibility of obtaining stipulations of fact and of the authenticity, accuracy, and admissibility of documents, which will avoid unnecessary proof;

(4) The limitation of the number of expert or other witnesses;

(5) The negotiation, compromise, or settlement of issues;

(6) The exchange of copies of proposed exhibits;

(7) The identification of documents or matters of which official notice may be requested;

(8) A schedule to be followed by the parties for completion of the actions decided at the conference; or

(9) Such other matters as may expedite and aid in the disposition of the proceeding.

No transcript or recording of such a conference shall be made, but the presiding officer shall prepare and file for the record a written summary if any action is taken at the conference, which shall incorporate any written stipulations or agreements made by the parties at the conference or as a result of the conference.

(b) *Manner of the prehearing conference.* (1) The prehearing conference

shall be conducted by telephone or correspondence unless the presiding officer determines that conducting the prehearing conference by audio-visual telecommunication:

(i) Is necessary to prevent prejudice to a party;

(ii) Is necessary because of a disability of any individual expected to participate in the prehearing conference; or

(iii) Would cost less than conducting the prehearing conference by telephone or correspondence. If the presiding officer determines that a prehearing conference conducted by audio-visual telecommunication would measurably increase the United States Department of Agriculture's cost of conducting the prehearing conference, the prehearing conference shall be conducted by personal attendance of any individual who is expected to participate in the prehearing conference, by telephone, or by correspondence.

(2) If the prehearing conference is not conducted by telephone or correspondence, the prehearing conference shall be conducted by audio-visual telecommunication unless the presiding officer determines that conducting the prehearing conference by personal attendance of any individual who is expected to participate in the prehearing conference:

(i) Is necessary to prevent prejudice to a party;

(ii) Is necessary because of a disability of any individual expected to participate in the prehearing conference; or

(iii) Would cost less than conducting the prehearing conference by audio-visual telecommunication.

[43 FR 30510, July 14, 1978, as amended at 60 FR 8466, Feb. 14, 1995]

§ 202.111 Rule 11: Hearing, oral or written.

(a) *When held.* A hearing, oral or written, shall be held unless:

(1) Each respondent admits or is deemed to admit sufficient allegations of the complaint to support the full amount claimed by the complainant as reparation;

(2) Each respondent admits liability to the complainant in the full amount claimed by the complainant as reparation;

(3) Before a hearing has been completed the parties agree in writing that the proceeding may be decided on the basis of the record as it stands at the time such agreement is filed; or

(4) Before a hearing has been completed the parties settle their dispute or the complainant withdraws the complaint.

(b) *Whether oral or written.* The hearing provided for in paragraph (a) of this section shall be oral if:

(1) $10,000 or more is in controversy and any respondent files a written request for an oral hearing with such respondent's answer; or

(2) $10,000 or more is in controversy and any complainant files a written request for an oral hearing on or before the 20th day after service on such complainant of notice that no respondent has filed a timely request for an oral hearing; or

(3) Less than $10,000 is in controversy and the presiding officer determines, upon written request by any party thereto, that an oral hearing is necessary to establish the facts and circumstances giving rise to the controversy. The hearing shall be written if not oral.

(c) *Withdrawal of request.* If $10,000 or more is in controversy and a party has timely filed a request for oral hearing, such party may withdraw such request at any time prior to completion of an oral hearing. If such a withdrawal leaves no pending request for oral hearing in the proceeding, and if the presiding officer has not decided that the hearing should be oral, each other party shall be served with notice of this and shall be given 20 days to request an oral hearing. If any party files a request for oral hearing in such time, the hearing shall be oral in accordance with paragraph (b) of this section.

(d) *Presiding Officer's recommendation.* The presiding officer may recommend voluntary withdrawal of a request for oral hearing, timely filed. Declining to make such withdrawal shall not affect the rights or interests of any party.

(e) *Representation.* Any party may appear in an oral hearing, or file evidence in a written hearing, in person or by counsel or other representative. For

unethical or contumacious conduct in or in connection with a proceeding, the presiding officer may preclude a person from further acting as attorney or representative for any party to the proceeding; any such order of the presiding officer shall be served on the parties; an appeal to the Judicial Officer may be taken from any such order immediately.

[51 FR 42083, Nov. 21, 1986, as amended at 55 FR 41184, Oct. 10, 1990]

§ 202.112 Rule 12: Oral hearing.

(a) *Time, place, and manner.* (1) If and when the proceeding has reached the stage where an oral hearing is to be held, the presiding officer shall set a time, place, and manner for oral hearing. The time shall be set based upon careful consideration to the convenience of the parties. The place shall be set in accordance with paragraph (a)(2) of this section and careful consideration to the convenience of the parties. The manner in which the hearing is to be conducted shall be determined in accordance with paragraphs (a)(3) and (a)(4) of this section.

(2) The place shall be set in accordance with paragraphs (e) and (f) of section 407 of the Act, if applicable. In essence, under paragraphs (e) and (f) of section 407 of the Act, if the complainant and the respondent, or all of the parties, if there are more than two, have their principal places of business or residence within a single unit of local government, a single geographical area within a State, or a single State, the oral hearing is to be held as near as possible to such places of business or residence, depending on the availability of an appropriate location for conducting the hearing. If the parties have such places of business or residence distant from each other, then paragraphs (e) and (f) of section 407 of the Act are not applicable.

(3) The oral hearing shall be conducted by audio-visual telecommunication unless the presiding officer determines that conducting the oral hearing by personal attendance of any individual who is expected to participate in the hearing:

(i) Is necessary to prevent prejudice to a party;

(ii) Is necessary because of a disability of any individual expected to participate in the hearing; or

(iii) Would cost less than conducting the hearing by audio-visual telecommunication. If the presiding officer determines that a hearing conducted by audio-visual telecommunication would measurably increase the United States Department of Agriculture's cost of conducting the hearing, the hearing shall be conducted by personal attendance of any individual who is expected to participate in the hearing or by telephone.

(4) The presiding officer may, in his or her sole discretion or in response to a motion by a party to the proceeding, conduct the hearing by telephone if the presiding officer finds that a hearing conducted by telephone:

(i) Would provide a full and fair evidentiary hearing;

(ii) Would not prejudice any party; and

(iii) Would cost less than conducting the hearing by audio-visual telecommunication or personal attendance of any individual who is expected to participate in the hearing.

(b) *Notice.* (1) A notice stating the time, place, and manner of oral hearing shall be served on each party prior to the time of the oral hearing. The notice shall state whether the oral hearing will be conducted by telephone, audio-visual telecommunication, or personal attendance of any individual expected to participate in the hearing. If any change is made in the time, place, or manner of the oral hearing, a notice of the change shall be served on each party prior to the time of the oral hearing as changed, unless the change is made during the course of an oral hearing and shown in the transcript or on the recording. Any party may waive such notice, in writing, or orally on the record at an oral hearing and shown in the transcript or on the recording.

(2) If the presiding officer orders an oral hearing, any party may move that the hearing be conducted by telephone or personal attendance of any individual expected to attend the hearing rather than by audio-visual telecommunication. Any motion that the hearing be conducted by telephone or personal attendance of any individual

expected to attend the hearing must be accompanied by a memorandum in support of the motion stating the basis for the motion and the circumstances that require the hearing to be conducted other than by audio-visual telecommunication.

(3) Within 10 days after the presiding officer issues a notice stating the manner in which the hearing is to be conducted, any party may move that the presiding officer reconsider the manner in which the hearing is to be conducted. Any motion for reconsideration must be accompanied by a memorandum in support of the motion stating the basis for the motion and the circumstances that require the hearing to be conducted other than in accordance with the presiding officer's notice.

(c) *Failure to appear.* If any party to the proceeding, after being duly notified, fails to appear at the oral hearing in person or by counsel or other representative, such party shall be deemed to have waived the right to add any further evidence to the record in the proceeding, or to object to the admission of any evidence; if the parties who are present are all adverse to such party, they shall have an election to present evidence, in whole or in part, in the form of oral testimony before the presiding officer, affidavits, or depositions.

(d) *Order of proceeding.* Complainant shall proceed first, if present at the commencement of the oral hearing.

(e) *Written statements of direct testimony.* (1) Except as provided in paragraph (e)(2) of this section, each party must exchange with all other parties a written narrative verified statement of the oral direct testimony that the party will provide at any hearing to be conducted by telephone; the direct testimony of each employee or agent of the party that the party will call to provide oral direct testimony at any hearing to be conducted by telephone; and the direct testimony of each expert witness that the party will call to provide oral direct testimony at any hearing to be conducted by telephone. The written direct testimony of witnesses shall be exchanged by the parties at least 10 days prior to the hearing. The oral direct testimony provided by a witness at a hearing conducted by telephone will be limited to the presentation of the written direct testimony, unless the presiding officer finds that oral direct testimony which is supplemental to the written direct testimony would further the public interest and would not constitute surprise.

(2) The parties shall not be required to exchange testimony in accordance with this paragraph if the hearing is scheduled to begin less than 20 days after the presiding officer's notice stating the time of the hearing.

(f) *Evidence*—(1) *In general.* The testimony of witnesses at an oral hearing shall be on oath or affirmation and subject to cross-examination. Any witness other than a party may be examined separately and apart from all other witnesses, in the discretion of the presiding officer. The presiding officer shall exclude evidence which is immaterial, irrelevant, or unduly repetitious, or which is not of the sort on which responsible persons are accustomed to rely, insofar as practicable.

(2) *Objections.* If a party objects to the admission of any evidence or to the limitation of the scope of any examination or cross-examination or to any other ruling of the presiding officer, such party shall state briefly the grounds of such objection, and the presiding officer shall rule on it. The transcript or recording shall include argument or debates on objections, except as ordered by the presiding officer, and shall include the ruling of the presiding officer. Objections not made before the presiding officer may not subsequently be relied on in the proceeding.

(3) *Offer of proof.* Whenever evidence is excluded by the presiding officer, the party offering such evidence may make an offer of proof. The offer of proof shall consist of a brief statement, which shall be included in the transcript or recording, describing the evidence excluded. If the evidence consists of a brief oral statement, it shall be included in full in the transcript or recording. If the evidence consists of an exhibit, it shall be marked for identification and inserted in the record. In either such event, if the judicial officer decides that the presiding officer's ruling in excluding the evidence was erroneous and prejudicial, such evidence shall be considered a part of the record.

If the taking of such evidence will consume a considerable length of time at the hearing, the presiding officer shall not allow the insertion of such evidence in full and, if the judicial officer decides that the presiding officer's ruling in excluding the evidence was erroneous and prejudicial, the hearing shall be reopened to permit the taking of such evidence.

(4) *Depositions and affidavits.* Except as is otherwise provided in these rules, admission of the deposition of any witness shall be subject to the provisions of rule 9, § 202.109, and affidavits, and statements under penalty of perjury as provided in 28 U.S.C. 1746, Pub. L. 94–550, may be admitted only if the evidence is otherwise admissible and no party objects.

(5) *Department records.* A true copy of any written entry in any record of the Department, made by an officer or employee of the Department in the course of the official duty of such officer or employee, and relevant to the issues involved in the hearing, shall be admissible as prima facie evidence of the facts stated in the record of the Department, without the production of such officer or employee.

(6) *Exhibits.* (i) For each exhibit offered by a party, copies in addition to the original shall be filed with the presiding officer for the use of all other parties to the proceeding, except where the presiding officer finds that the furnishing of copies is impracticable. The presiding officer shall tell the parties the number of copies required to be filed, make the proper distribution of the copies, and have this noted on the record.

(ii) If the testimony of a witness refers to any document, the presiding officer shall determine whether it shall be produced at the hearing and made a part of the record as an exhibit, or whether it shall be incorporated in the record by reference.

(iii) If relevant and material matter is embraced in a document containing irrelevant or immaterial matter, such irrelevant or immaterial matter shall be designated by the party offering the document in evidence, and shall be segregated and excluded, insofar as practicable.

(g) *Subpoenas*—(1) *Issuance.* The attendance and testimony of witnesses and the production of documentary evidence, from any place in the United States, on behalf of any party to the proceeding, may be required by subpoena at any designated place for oral hearing. Subpoenas may be issued by the presiding officer, on a written application filed by a party, showing the grounds and necessity thereof, and, with respect to subpoenas for the production of documentary evidence, showing their competency, relevancy, and materiality and the necessity for their production. Subpoenas may be issued on the motion of the presiding officer.

(2) *Service; proof of service.* A subpoena may be served by any natural person over the age of 18 years. The party at whose instance a subpoena is issued shall be responsible for serving it, however, at the request of such party the Secretary will attempt to serve it.

(h) *Oral argument.* The presiding officer shall permit oral argument by the parties or their counsel who are present at an oral hearing, but may limit such argument to any extent that the presiding officer finds necessary for the expeditious or proper disposition of the case.

(i) *Transcript or recording.* (1) Hearings to be conducted by telephone shall be recorded verbatim by electronic recording device. Hearings conducted by audio-visual telecommunication or the personal attendance of any individual who is expected to participate in the hearing shall be transcribed, unless the presiding officer finds that recording the hearing verbatim would expedite the proceeding and the presiding officer orders the hearing to be recorded verbatim. The presiding officer shall certify that to the best of his or her knowledge and belief any recording made pursuant to this paragraph with exhibits that were accepted into evidence is the record of the hearing.

(2) If a hearing is recorded verbatim, a party requests the transcript of a hearing or part of a hearing, and the presiding officer determines that the disposition of the proceeding would be expedited by a transcript of the hearing or part of a hearing, the presiding

officer shall order the verbatim transcription of the recording as requested by the party.

(3) Parties to the proceeding who desire copies of the transcript or recording of the oral hearing may make arrangements with the reporter, who will furnish and deliver such copies direct to such parties, upon receipt from such parties of payment for the transcript or recording, at the rate provided by the contract between the reporter and the Department for such reporting service.

(j) *Filing, and presiding officer's certificate, of the transcript or recording.* As soon as practicable after the close of the oral hearing, the reporter shall transmit to the presiding officer the original transcript or recording of the testimony, and as many copies of the transcript or recording as may be required by paragraph (j) of this section for the area offices of the Agency and as may be required for the Washington office of the Agency. At the same time the reporter shall also transmit a copy of the transcript or recording to each party who shall have arranged and paid for it, as provided in paragraph (h) of this section. Upon receipt of the transcript or recording, the presiding officer shall attach to the original transcript or recording a certificate stating that, to the best of the presiding officer's knowledge and belief, the transcript or recording is a true, correct, and complete transcript or recording of the testimony given at the hearing and that the exhibits mentioned in it are all the exhibits received in evidence at the hearing, with such exceptions as the certificate shall specify. Such certificate shall be served on each party and a copy thereof shall be attached to each copy of the transcript or recording received by the presiding officer. In accordance with such certificate the presiding officer shall note, on the original transcript or recording, each correction detailed in such certificate by adding or crossing out (but without obscuring the texts as originally transcribed or recorded) at the appropriate places any words necessary to make the text conform to the correct meaning, as certified by the presiding officer. The presiding officer shall send the copies of the transcript or recording to the hearing clerk who shall send them to the Agency.

(k) *Keeping of copies of the transcript or recording.* During the period in which the proceeding has an active status in the Department, a copy of the transcript or recording shall be kept at the area office of the Agency most convenient to the respondent; however, if there are two or more respondents and they are located in different regions, such copy of the transcript or recording shall be kept at the area office of the Agency nearest to the place where the hearing was held. In addition, a copy of the transcript or recording shall be kept at the area office of the Agency most convenient to the complainant. Any such copy shall be available for examination during official hours of business at the area office, but shall remain the property of the Department and shall not be removed from such office.

[43 FR 30510, July 14, 1978, as amended at 55 FR 41184, Oct. 10, 1990; 60 FR 8466, Feb. 14, 1995]

§ 202.113 Rule 13: Written hearing.

(a) *Evidence.* As used in this section, the term ''evidence'' shall mean depositions, affidavits, or statements under penalty of perjury as provided in 28 U.S.C. 1746, Pub. L. 94–550, of persons having knowledge of the facts, or documents properly identified by such deposition, affidavit, or statement, or otherwise authenticated in such a manner that they would be admissible in evidence at an oral hearing, except as provided hereinafter. Testimony on deposition, to the extent credible, shall be given greater weight as evidence, than such affidavits or statements. In a case in which a party, entitled to oral hearing as provided in rule 11, § 202.111, withdraws such party's request for oral hearing on condition that only depositions be used if a written hearing is held, only depositions, and documents properly identified therein, shall be made a part of the record as evidence by the parties if a written hearing is held.

(b) *Verification.* Any facts must be verified, by oath or affirmation before

a person legally authorized to administer oaths or before a person designated by the Secretary for the purpose (except in the case of a statement under penalty of perjury as provided in 28 U.S.C. 1746, Pub. L. 94–550), by a person who states, in the deposition, affidavit, or statement, that such person has actual knowledge of the facts. Except under unusual circumstances, which shall be set forth in the deposition, affidavit, or statement, any such person shall be one who would appear as a witness if an oral hearing were held.

(c) *Complainant's evidence.* The complainant shall be served with notice of an opportunity to file evidence. Within 20 days after such service, the complainant may file evidence. What the complainant files in response to that notice shall be served promptly on the respondent.

(d) *Respondent's evidence.* After expiration of the time for the filing of complainant's evidence, the respondent shall be served with notice of an opportunity to file evidence. Within 20 days after such service, the respondent may file evidence. What the respondent files in response to that notice shall be served promptly on the complainant.

(e) *Complainant's rebuttal.* If the respondent files anything pursuant to paragraph (d) of this section, the complainant shall be served with notice of an opportunity to file evidence in rebuttal of what the respondent has filed. Within 20 days after such service, the complainant may file such evidence, which shall be confined strictly to rebuttal of what the respondent has filed. What the complainant files in response to that notice shall be served promptly on the respondent.

(f) *Failure to file.* Failure to file any evidence authorized under this section, within the time prescribed, shall constitute a waiver of the right to file such evidence.

(g) *Extension of time for depositions.* If any party timely files an application for an order for the taking of testimony by deposition pursuant to rule 9, § 202.109, time for the filing of such party's evidence shall be extended as reasonable, to permit consideration of the application, and taking of depositions if ordered.

(h) *Investigation report.* No provision of this rule 13 shall change the status of an investigation report served on the parties and made a part of the record pursuant to rule 4, § 202.104.

[43 FR 30510, July 14, 1978, as amended at 55 FR 41184, Oct. 10, 1990]

§ 202.114 Rule 14: Post-hearing procedure.

(a) *Oral hearing.* Any party present or represented at an oral hearing, desiring to file any written argument or brief, proposed findings of fact, conclusions, and order, or statement of objections to rulings made by the presiding officer, must so inform the presiding officer at the oral hearing; upon being so informed, the presiding officer shall set a reasonable time for the filing of such documents, and state it on the record at the oral hearing.

(b) *Written hearing.* After filing of the last evidence in a written hearing, notice shall be served on each party that such party may file, within 20 days after such service on such party, written argument of brief, proposed findings or fact, conclusions, and order.

(c) *Service; delay in preparation of report.* If any such document is filed by any party, it shall be served on all other parties. The report shall not be prepared before expiration of such time for filing.

[43 FR 30510, July 14, 1978, as amended at 55 FR 41184, Oct. 10, 1990]

§ 202.115 Rule 15: Submission for final consideration.

(a) *Report.* The presiding officer, with the assistance and collaboration of such employees of the Department as may be assigned for the purpose, shall prepare a report. The report shall be prepared on the basis of the evidence in the record, including the investigation report if one is prepared by the agency head and served on the parties, and any allegations admitted or deemed to be admitted, and any stipulations. The report shall be prepared in the form of a final order for signature by the judicial officer, and shall be filed with the hearing clerk. The report shall not be served on the parties unless and until it is signed by the judicial officer.

(b) *Record.* At the same time as the report is filed with the hearing clerk,

the record shall also be filed with the hearing clerk. The record shall include: Pleadings; motions and requests filed and rulings thereon; the investigation report if one is prepared by the agency head and served on the parties; the transcript or recording of an oral hearing, and exhibits received, if an oral hearing was held; evidence filed by the parties if a written hearing was held; documents filed in connection with pre-hearing conferences; any proposed findings of fact, conclusions and orders, statements of objections, and briefs; any stipulations; and proof of service.

(c) *Submission to judicial officer.* Unless the hearing clerk reasonably believes that the record is not complete and in proper order, the record and the report shall be submitted to the judicial officer for decision.

(d) *Oral argument.* There shall be no right to oral argument other than that provided in rule 12(h), § 202.112(h).

[43 FR 30510, July 14, 1978, as amended at 60 FR 8467, Feb. 14, 1995]

§ 202.116 Rule 16: Issuance of order.

(a) As soon as practicable after the receipt of the record and report from the hearing clerk, the judicial officer, on the basis of and after due consideration of the record, shall issue an order in the proceeding, which shall be served on the parties.

(b) If the judicial officer deems it advisable to do so, the order may be made a tentative order. In such event, a presiding officer shall be assigned and the tentative order shall be served on each party, and each party shall have 20 days in which to file written exceptions to it, and arguments or briefs in support of such exceptions. If no party timely files exceptions, the tentative order shall automatically become the final order in the proceeding, and notice of such fact shall be served on the parties. If any party timely files such exceptions, they shall be handled in the same manner as a petition filed under rule 17, § 202.117.

§ 202.117 Rule 17: Petition to reopen a hearing; to rehear or reargue a proceeding; to reconsider an order; or to set aside a default order.

(a) *Filing of petition*—(1) *To reopen a hearing.* Any party may file a petition to reopen a hearing to take further evidence, at any time prior to the issuance of the final order, or prior to a tentative order becoming final. Such a petition must state the nature and purpose of the evidence to be offered, show that it is not merely cumulative, and state a good reason why it was not offered at the hearing if oral, or filed in the hearing if written.

(2) *To rehear or reargue a proceeding or reconsider an order.* Any party may file a petition to rehear or reargue a proceeding or reconsider an order of the judicial officer, at any time within 20 days after service on such party of such order. Such a petition must specify the matters claimed to have been erroneously decided, and the basis for the petitioner's claim that such matters were erroneously decided.

(3) *To set aside a default order.* Any respondent against whom an order is issued by the judicial officer, upon failure to file an answer as required, may file a petition to set aside such order, at any time within 20 days after service on such respondent of such order. Such a petition must state a good reason why an answer was not filed as required.

(b) *Brief or memorandum of law.* If such a petitioner wishes to file a brief or memorandum of law in support of such a petition, it must be filed with such petition.

(c) *Procedure.* A presiding officer shall be assigned upon the filing of any such petition, or upon notice to the hearing clerk (which may be written or oral, or by telephone) that any party intends to file any such petition. The party filing any such petition shall be referred to as the complainant or respondent, depending on the original designation of such party in the proceeding; such party shall have the burden of establishing that such petition should be granted. If a petition to reopen is timely filed, the order shall not be issued pending decision whether to grant or deny the petition. If a petition to rehear or reargue or reconsider, or to set aside a default order, is timely filed, operation of the order shall be stayed automatically pending decision whether to grant or deny it; if such a petition is not timely filed, operation of the order shall not be stayed unless

the Judicial Officer shall determine otherwise.

(d) *Service; answer.* No such petition shall be granted unless it, with the brief or memorandum of law in support of it, if any, is first served on each party to the proceeding other than the one filing it. Each such other party, within 20 days after such service on such party, may file an answer to such petition. If any such party wishes to file a brief or memorandum of law in support of such an answer, it must be filed with such answer. Any such answer, with the brief or memorandum of law in support of it, if any, shall be served on each party to the proceeding other than the one filing it. Any such petition may be denied without such service.

(e) *Submission for decision; service of order.* The presiding officer shall prepare a recommendation with respect to the petition, and submit it to the judicial officer for decision. Such a recommendation shall be prepared in the form of a final order for signature by the judicial officer. It shall not be served on the parties unless and until it is signed by the judicial officer. The order of the judicial officer shall be served on the parties.

(f) *Practice upon decision.* If the judicial officer decides to reopen a hearing, or to rehear or permit reargument of a proceeding, or to set aside a default order, a presiding officer shall be assigned and the rules of practice shall be followed thereafter as applicable.

§ 202.118 Rule 18: Presiding officer.

(a) *Powers.* Subject to review as provided elsewhere in these rules, the presiding officer assigned to any proceeding shall have power to:

(1) Set the time, place, and manner of a prehearing conference and an oral hearing, adjourn the oral hearing from time to time, and change the time, place, and manner of oral hearing;

(2) Administer oaths and affirmations;

(3) Issue subpoenas requiring the attendance and testimony of witnesses and the production of documentary evidence at an oral hearing;

(4) Summon and examine witnesses and receive evidence at an oral hearing;

(5) Take or order the taking of depositions;

(6) Admit or exclude evidence;

(7) Hear oral argument on facts or law;

(8) Require each party to provide all other parties and the presiding officer with a copy of any exhibit that the party intends to introduce into evidence prior to any oral hearing to be conducted by telephone or audio-visual telecommunication;

(9) Require each party to provide all other parties with a copy of any document that the party intends to use to examine a deponent prior to any deposition to be conducted by telephone or audio-visual telecommunication;

(10) Require that any hearing to be conducted by telephone or audio-visual telecommunication be conducted at locations at which the parties and the presiding officer are able to transmit and receive documents during the hearing;

(11) Require that any deposition to be conducted by telephone or audio-visual telecommunication be conducted at locations at which the parties are able to transmit and receive documents during the deposition; and

(12) Do all acts and take all measures necessary for the maintenance of order and the efficient conduct of the proceeding, including the exclusion of contumacious counsel or other persons.

(b) *Motions and requests.* The presiding officer is authorized to rule on all motions and requests filed in the proceeding prior to submission of the presiding officer's report to the judicial officer, *Provided,* That a presiding officer is not authorized to dismiss a complaint. Submission or certification of any question to the judicial officer, prior to submission of the report, shall be in the discretion of the presiding officer.

(c) *Reassignment.* For any good reason, including absence, illness, resignation, death, or inability to act, of the attorney assigned to act as a presiding officer in any proceeding under these rules, the powers and duties of such attorney in the proceeding may be assigned to any other attorney who is employed in the Office of the General Counsel of the Department, without abatement of the proceeding.

(d) *Disqualification.* No person shall be assigned to act as a presiding officer in any proceeding who (1) has any material pecuniary interest in any matter or business involved in the proceeding; (2) is related within the third degree by blood or marriage to any party to the proceeding; or (3) has any conflict of interest which might impair such person's objectivity in the proceeding. A person assigned to act as a presiding officer shall ask to be replaced, in any proceeding in which such person believes that reason exists for disqualification of such person.

(e) *Procedure on petition for disqualification.* Any party may file a petition for disqualification of the presiding officer, which shall set forth with particularity the grounds of alleged disqualification. Any such petition shall be filed with the hearing clerk, who shall immediately transmit it to the judicial officer and inform the presiding officer. The record of the proceeding also shall immediately be transmitted to the judicial officer. After such investigation or hearing as the judicial officer deems necessary, the judicial officer shall either deny the petition or direct that another presiding officer be assigned to the proceeding. The petition, and notice of the order of the judicial officer, shall be made a part of the record and served on the parties; if any record is made on such a petition, it shall be a part of the record of the proceeding.

[43 FR 30510, July 14, 1978, as amended at 60 FR 8467, Feb. 14, 1995]

§ 202.119 Rule 19: Fees of witnesses.

Witnesses subpoenaed before the presiding officer, and witnesses whose depositions are taken, shall be entitled to the same fees and mileage as are paid for like services in the courts of the United States. Fees and mileage shall be paid by the party at whose instance the witness appears or the deposition is taken.

§ 202.120 Rule 20: Official notice.

Official notice shall be taken of such matters as are judicially noticed by the courts of the United States and of any other matter of technical or scientific fact of established character: *Provided,* That the parties shall be given notice of matters so noticed, and shall be given adequate opportunity to show that such facts are erroneously noticed.

§ 202.121 Rule 21: Intervention.

At any time after docketing of a proceeding and before commencement of a hearing, oral or written, therein, the presiding officer may, upon petition, and for good cause shown, permit any person to intervene therein. The petition shall state with preciseness and particularity: (a) The petitioner's relationship to the matters involved in the proceeding; (b) the nature of the material the petitioner intends to present in evidence; (c) the nature of the argument the petitioner intends to make; and (d) the reasons why the petitioner should be allowed to intervene. Any such petition, and notice of the order thereon, shall be served on the parties and made a part of the record in the proceeding.

§ 202.122 Rule 22: Ex parte communications.

(a) At no stage of the proceeding between its docketing and the issuance of the final decision shall the presiding officer or judicial officer discuss ex parte the merits of the proceeding with any party, or attorney or representative of a party: *Provided,* That procedural matters shall not be included within this limitation; and *Provided further,* That the presiding officer or judicial officer may discuss the merits of the case with such a person if all parties to the proceeding or their attorneys or representatives have been served with notice and an opportunity to participate. A memorandum of any such discussion shall be included in the record.

(b) No party, or attorney or representative of a party, or other person not an employee of the Department, shall make or knowingly cause to be made to the presiding officer or judicial officer an ex parte communication relevant to the merits of the proceeding.

(c) If the presiding officer or judicial officer receives an ex parte communication in violation of this section,

the one who receives the communication shall place in the public record of the proceeding:

(1) Such communication if written, or a memorandum stating the substance of such communication if oral; and

(2) A copy of any written response or a memorandum stating the substance of any oral response thereto.

(d) Copies of all such items placed or included in the record, as provided in this section, shall be served on all parties.

(e) For purposes of this section ''ex parte communication'' means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include a request for a status report on any matter or the proceeding.

§ 202.123 Rule 23: Action by Secretary.

The Secretary may act in the place and stead of a presiding officer or the judicial officer in any proceeding hereunder, or any matter in connection therewith.

RULES OF PRACTICE APPLICABLE TO ALL OTHER PROCEEDINGS

SOURCE: Sections 202.200 and 202.210 were added at 72 FR 19109, Apr. 17, 2007, unless otherwise noted.

§ 202.200 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in Subpart H of Part 1, Subtitle A, Title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the Packers and Stockyards Act, as amended (7 U.S.C. 181 *et seq.*). In addition, the Supplemental Rules of Practice set forth in this part shall be applicable to such proceedings.

§ 202.210 Stipulations.

(a) The Administrator may enter into a stipulation with any person operating subject to the Packers and Stockyards Act, as amended (P&S Act), prior to issuing a complaint that seeks a civil penalty against that person.

(1) The Administrator will give the person notice of an alleged violation of the P&S Act or regulations and provide an opportunity for a hearing;

(2) The person has the option to expressly waive the opportunity for a hearing and agree to pay a specified civil penalty within a designated time;

(3) The Administrator will agree to settle the matter by accepting payment of the specified civil penalty within a designated time;

(4) If the person does not agree to the stipulation, or does not pay the penalty within the specified time, the Administrator may issue an administrative complaint citing the alleged violation; and

(5) The civil penalty that the Administrator proposed in a stipulation agreement has no bearing on the civil penalty amount that may be sought in a formal administrative proceeding against the same person for the same alleged violation.

(b) [Reserved]

PART 203—STATEMENTS OF GENERAL POLICY UNDER THE PACKERS AND STOCKYARDS ACT

Sec.

AUTHORITY: 7 CFR 2.22 and 2.81.

§ 203.1 [Reserved]

§ 203.2 Statement of general policy with respect to the giving by meat packers of meat and other gifts to Government employees.

(a) In recent months, the Department has received information, confirmed by investigation, that a number of packers subject to the Packers and Stockyards Act have made gifts of meat to Government employees responsible for conducting service activities of the Department. Such gifts have the implications of fraud, even if not made specifically for the purpose of influencing these employees in the performance of their duties.

(b) It is a violation of the Meat Inspection Act for any person, firm, or corporation to give to any employee of the Department performing duties under such act anything of value with intent to influence such employee in the discharge of his duties, or for such employee to receive from any person, firm, or corporation engaged in interstate or foreign commerce any gift given with any intent or purpose whatsoever (21 U.S.C. 90). Under the Federal meat grading regulations, the giving or attempting to give by a packer of anything of value to any employee of the Department authorized to perform any function under such regulations is a basis for the withdrawal of Federal meat grading service (7 CFR 53.13). The receiving by an employee of the Department of any gift from any person for whom grading, inspection, or other service work is performed is specifically prohibited by Departmental regulations.

(c) Upon the basis of paragraphs (a) and (b) of this section, it is the view of the Department that it is an unfair and deceptive practice in violation of section 202(a) of the Packers and Stockyards Act (7 U.S.C. 192(a)) for any person subject to the provisions of Title II of said Act to give or offer to give meat, money, or anything of value to any Government employee who performs inspection, grading, reporting, or regulatory duties directly relating to the purchase or sale of livestock or the preparation or distribution of meats, meat food products, livestock products in unmanufactured form, poultry or poultry products.

(Sec. 407, 42 Stat. 169; 7 U.S.C. 228; 9 CFR 201.3)

[26 FR 710, Jan. 25, 1961; 29 FR 4081, Mar. 28, 1964]

§ 203.3 [Reserved]

§ 203.4 Statement with respect to the disposition of records by packers, live poultry dealers, stockyard owners, market agencies and dealers.

(a) *Records to be kept.* Section 401 of the Packers and Stockyards Act (7 U.S.C. 221) provides, in part, that every packer, live poultry dealer, stockyard owner, market agency, and dealer shall keep such accounts, records, and memoranda as fully and correctly disclose all transactions involved in his business, including the true ownership of such business by stockholding or otherwise. In order to properly administer the P&S Act, it is necessary that records be retained for such periods of time as may be required to permit the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) a reasonable opportunity to examine such records. Section 401 of the Act does not, however, provide for the destruction or disposal of records. Therefore, the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) has formulated this policy statement to provide guidance as to the periods of time after which records may be disposed of or destroyed.

(b) *Records may be disposed of after two years except as otherwise provided.* Except as provided in paragraph (c) of this section, each packer, live poultry dealer, stockyard owner, market agency, and dealer may destroy or dispose of accounts, records, and memoranda

which contain, explain, or modify transactions in its business subject to the Act after such accounts, records, and memoranda have been retained for a period of two full years; *Provided*, That the following records made or kept by a packer may be disposed of after one year: cutting tests; departmental transfers; buyers' estimates; drive sheets; scale tickets received from others; inventory and products in storage; receiving records; trial balances; departmental overhead or expense recapitulations; bank statements, reconciliations and deposit slips; production or sale tonnage reports (including recapitulations and summaries of routes, branches, plants, etc.); buying or selling pricing instructions and price lists; correspondence; telegrams; teletype communications and memoranda relating to matters other than contracts, agreements, purchase or sales invoices, or claims or credit memoranda; and *Provided further*, That microfilm copies of records may be substituted for and retained in lieu of the actual records.

(c) *Retention for longer periods may be required.* The periods specified in paragraph (b) of this section shall be extended if the packer, live poultry dealer, stockyard owner, market agency, or dealer is notified in writing by the Administrator that specified records should be retained for a longer period pending the completion of any investigation or proceedings under the Act.

(d) *Unauthorized disposal of records.* If it is found that any person subject to the Act has disposed of accounts, records, and memoranda which are necessary to fully and correctly disclose all transactions in its business prior to the periods specified in this statement, consideration will be given to the issuance of a complaint charging a violation of section 401 of the Act and seeking an appropriate order. The administrative proceeding initiated will be conducted in accordance with the Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary (7 CFR 1.130 *et seq.*).

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 228, 7 U.S.C. 222, and 15 U.S.C. 46)

[49 FR 6085, Feb. 17, 1984, as amended at 54 FR 16357, Apr. 24, 1989; 68 FR 75388, Dec. 31, 2003]

§ 203.5 Statement with respect to market agencies paying the expenses of livestock buyers.

It has become a practice in certain areas of the country for market agencies, engaged in the business of selling consigned livestock on a commission basis, to pay certain of the business or personal expenses incurred by buyers attending livestock sales conducted by such market agencies, such as, expenses for meals, lodging, travel, entertainment and long distance telephone calls. Investigation by the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs), discloses that this practice tends to become a method of competition between similarly engaged market agencies and results in undue and unreasonable cost burdens on such market agencies and the livestock producers who sell their livestock through such market agencies.

It is the view of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) that it constitutes violations of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*), for any market agency engaged in the business of selling consigned livestock on a commission basis, to pay, directly or indirectly, any personal or business expenses of livestock buyers attending sales conducted by such market agency. In the future, if any market agency engages in such practice, consideration will be given by the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) to the issuance of a complaint charging the market agency with violation of the Act. In the formal administrative proceeding initiated by any such complaint, the Judicial Officer of the Department will determine, after full hearing, whether the market agency has violated the Act and should be

ordered to cease and desist from continuing such violation, and whether the registration of such market agency should be suspended for a reasonable period of time.

(Secs. 407, 4, 42 Stat. 169, 72 Stat. 1750; 7 U.S.C. 228. Interprets or applies secs. 304, 307, 312, 42 Stat. 164, 165, 167; 7 U.S.C. 205, 208, 213)

[29 FR 311, Jan. 14, 1964; 29 FR 3304, Mar. 12, 1964, as amended at 32 FR 7700, May 26, 1967]

§ 203.6 [Reserved]

§ 203.7 Statement with respect to meat packer sales and purchase contracts.

(a) The Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) receives numerous complaints concerning the failure or refusal of buyers to pay the full purchase price for, or to accept delivery of, their purchases of meat and meat food products and sellers failing to meet contractual specifications. Most such complaints arise out of disputes concerning condition, grade, weight, or shipping instructions.

(b) It is believed that both seller and buyer should take the following points into consideration when selling and buying meat and meat food products:

(1) *Terms of shipment and time of arrival.* Terms and conditions of shipment and delivery should be specified in the contract and both parties should understand fully all terms and conditions of the contract. Any deviation from normal practices, such as a guaranty by the shipper as to the date of arrival at destination, or a deviation from the normal meaning of terms, should also be fully understood and made a part of the contract.

(2) *Quality and condition.* (i) A seller has the responsibility of making certain that the meat and meat food products shipped are in accordance with the terms of the contract specifications.

(ii) When a buyer believes that the shipment does not meet the terms of the contract, he should immediately contact the seller or the seller's agent and advise him of the nature of the complaint. This affords the seller an opportunity to renegotiate the contract, to personally inspect the meat or meat food products, or to have an impartial party inspect or examine the meat or meat food products. Inspection and examination service of this type is available nationally through the USDA meat grading service and locally through various impartial persons or agencies.

(iii) All terms of a transaction should be made clear in the contract, whether written or verbal. If there is any chance of misunderstanding, a written confirmation should be exchanged between the parties. In any case where a contract dispute cannot be settled between the parties and either party intends to file a complaint, such complaint should be brought to the attention of the nearest Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) area office as soon as possible. However, a concerted effort on the part of both buyer and seller to negotiate clear and complete contracts will greatly reduce misunderstandings which can result in the filing of complaints with the Administration.

(c) If the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) has reason to believe that any packer unjustifiably (1) has refused to pay the contractual price for meat or meat food products purchased, (2) has refused to accept a shipment of meat or meat food products, or (3) has failed to ship meat or meat food products in accordance with the terms of the contract specifications, consideration will be given to the issuance of a complaint charging the packer with violation of section 202 of the Act. In the formal administrative proceeding initiated by any such complaint, the Judicial Officer of the Department will determine, upon the basis of the record in the proceeding, whether the packer has violated the Act and should be ordered to cease and desist from continuing such violation.

(Secs. 407(a), 4, 42 Stat. 169, 72 Stat. 1750; 7 U.S.C. 228(a). Interprets or applies sec. 202, 42 Stat. 161 *et seq.*, as amended; 7 U.S.C. 192)

[30 FR 14966, Dec. 3, 1965, as amended at 32 FR 7701, May 26, 1967]

§§ 203.8–203.9 [Reserved]

§ 203.10 Statement with respect to insolvency; definition of current assets and current liabilities.

(a) Under the Packers and Stockyards Act, 1921, as amended and supplemented (7 U.S.C. 181 *et seq.*), the principal test of insolvency is to determine whether a person's current liabilities exceed his current assets. This current ratio test of insolvency under the Act has been reviewed and affirmed by a United States Court of Appeals. *Bowman v. United States Department of Agriculture,* 363 F. 2d 81 (5th Cir. 1966).

(b) For the purposes of the administration of the Packers and Stockyards Act, 1921, the following terms shall be construed, respectively, to mean:

(1) *Current assets* means cash and other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business, which is considered to be one year.

(2) *Current liabilities* means obligations whose liquidation is reasonably expected to require the use of existing resources principally classifiable as current assets or the creation of other current liabilities during the one year operating cycle of the business.

(c) The term current assets generally includes: (1) Cash in bank or on hand; (2) sums due a market agency from a custodial account for shippers' proceeds; (3) accounts receivable, if collectible; (4) notes receivable and portions of long-term notes receivable within one year from date of balance sheet, if collectable; (5) inventories of livestock acquired for purposes of resale or for purposes of market support; (6) feed inventories and other inventories which are intended to be sold or consumed in the normal operating cycle of the business; (7) accounts due from employees, if collectable; (8) accounts due from officers of a corporation, if collectable; (9) accounts due from affiliates and subsidiaries of corporations if the financial position of such subsidiaries and affiliates justifies such classification; (10) marketable securities representing cash available for current operations and not otherwise pledged as security; (11) accrued interest receivable; and (12) prepaid expenses.

(d) The term current assets generally excludes: (1) Cash and claims to cash which are restricted as to withdrawal, such as custodial funds for shippers' proceeds and current proceeds receivable from the sale of livestock sold on a commission basis; (2) investments in securities (whether marketable or not) or advances which have been made for the purposes of control, affiliation, or other continuing business advantage; (3) receivables which are not expected to be collected within 12 months; (4) cash surrender value of life insurance policies; (5) land and other natural resources; and (6) depreciable assets.

(e) The term current liabilities generally includes: (1) Bank overdrafts (per books); (2) amounts due a custodial account for shippers' proceeds; (3) accounts payable within one year from date of balance sheet; (4) notes payable or portions thereof due and payable within one year from date of balance sheet; (5) accruals such as taxes, wages, social security, unemployment compensation, etc., due and payable as of the date of the balance sheet; and (6) all other liabilities whose regular and ordinary liquidation is expected to occur within one year.

(Sec. 407(a), 42 Stat. 169, 72 Stat. 1750; 7 U.S.C. 228(a). Interprets or applies secs. 202, 307, 312, 502, 505; 42 Stat. 161 *et seq.*, as amended; 7 U.S.C. 192, 208, 213, 218a, 218d)

[32 FR 6901, May 5, 1967]

§ 203.11 [Reserved]

§ 203.12 Statement with respect to providing services and facilities at stockyards on a reasonable and nondiscriminatory basis.

(a) Section 304 of the Packers and Stockyards Act (7 U.S.C. 205) provides that: ''All stockyard services furnished pursuant to reasonable request made to a stockyard owner or market agency at such stockyard shall be reasonable and nondiscriminatory and stockyard services which are furnished shall not be refused on any basis that is unreasonable or unjustly discriminatory * * *.''

(b) Section 305 of the Act (7 U.S.C. 206) states that: ''All rates or charges made for any stockyard services furnished at a stockyard by a stockyard

owner or market agency shall be just, reasonable, and nondiscriminatory * * *.''

(c) Section 307 (7 U.S.C. 208) provides that: ''It shall be the duty of every stockyard owner and market agency to establish, observe, and enforce just, reasonable, and nondiscriminatory regulations and practices in respect to the furnishing of stockyard services * * *.''

(d) Section 312(a) (7 U.S.C. 213(a)) provides that: ''It shall be unlawful for any stockyard owner, market agency, or dealer to engage in or use any unfair, unjustly discriminatory, or deceptive practice or device in connection with determining whether persons should be authorized to operate at the stockyards, or with the receiving, marketing, buying, or selling on a commission basis or otherwise, feeding, watering, holding, delivery, shipment, weighing or handling, in commerce, of livestock.''

(e) Section 301(b) (7 U.S.C. 201(b)) defines ''stockyard services'' as any ''services or facilities furnished at a stockyard in connection with the receiving, buying, or selling on a commission basis or otherwise, marketing, feeding, watering, holding, delivery, shipment, weighing, or handling, in commerce, of livestock.''

(f) It is the view of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) that it is a violation of sections 304, 307, and 312(a) of the Act for a stockyard owner or market agency to discriminate, in the furnishing of stockyard services or facilities or in establishing rules or regulations at the stockyard, because of race, religion, color, or national origin of those persons using the stockyard services or facilities. Such services and facilities include, but are not limited to, the restaurant, restrooms, drinking fountains, lounge accommodations, those furnished for the selling, weighing, or other handling of the livestock, and facilities for observing such services.

(g) If the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) has reason to believe that any stockyard owner or market agency has so discriminated in the furnishing of stockyard services or facilities, consideration will be given to the issuance of a complaint charging the stockyard or market agency with violations of the Act.

(Sec. 407(a), 42 Stat. 159, 72 Stat. 1750; 7 U.S.C. 228(a). Interprets or applies secs. 304, 307, 312, 42 Stat. 161 *et seq.*, as amended, 7 U.S.C. 205, 208, 213)

[33 FR 17621, Nov. 26, 1968]

§ 203.13 [Reserved]

§ 203.14 Statement with respect to advertising allowances and other merchandising payments and services.

The Guidelines

1. *Who is a customer?* (a) A *customer* is a person who buys for resale directly from the packer, or through the packer's agent or broker; and in addition, a customer is any buyer of the packer's product for resale who purchases from or through a wholesaler or other intermediate reseller.

(NOTE: In determining whether a packer has fulfilled its obligations toward its customers, the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) will recognize that there may be some exceptions to this general definition of ''customer.'' For example, the purchaser of distress merchandise would not be considered a ''customer'' simply on the basis of such purchase. Similarly, a retailer who purchases solely from other retailers or one who makes only sporadic purchases, or one who does not regularly sell the packer's product or who is a type of retail outlet not usually selling such products will not be considered a ''customer'' of the packer unless the packer has been put on notice that such retailer is selling its product.)

(b) *Competing customers* are all businesses that compete in the resale of the packer's products of like grade and quality at the same functional level of distribution, regardless of whether they purchase direct from the packer or through some intermediary.

Example: A packer sells directly to some independent retailers, sells to the headquarters of chains and of retailer-owned cooperatives, and also sells to wholesalers. The direct-buying independent retailers, the headquarters of chains and of retailer-owned cooperatives, and the wholesalers' independent retailer customers are customers of the packer. Individual retail outlets which are part of the chains or members of the retailer-owned cooperatives are not customers of the packer.

2. *Definition of services. Services* are any kind of advertising or promotion of a packer's product, including but not limited to,

cooperative advertising, handbills, window and floor displays, demonstrators and demonstrations, customer coupons, and point of purchase activity.

3. *Need for a plan.* If a packer makes payments or furnishes services, it should do so under a plan that meets several requirements. If there are many competing customers to be considered, or if the plan is at all complex, the packer would be well advised to put its plan in writing. The requirements are:

(a) Proportionally equal terms—The payments or services under the plan should be made available to all competing customers on proportionally equal terms. This means that payments or services should be made proportionately on some basis that is fair to all customers who compete in the resale of the packer's products. No single way to achieve the proper proportion is prescribed, and any method that treats competing customers on proportionally equal terms may be used. Generally, this can best be done by basing the payments made or the services furnished on the dollar volume or on the quantity of goods purchased during a specified period. Other methods which are fair to all competing customers are also acceptable.

Example 1: A packer may properly offer to pay a specified part (say 50 percent) of the cost of local advertising up to an amount equal to a set percentage (such as 5 percent) of the dollar volume of such purchases during a specified time.

Example 2: A packer may properly place in reserve for each customer a specified amount of money for each unit purchased and use it to reimburse those customers for the cost of advertising and promoting the packer's product during a specified time.

Example 3: A packer's plan should not provide an allowance on a basis that has rates graduated with the amount of goods purchased, as for instance, 1 percent of the first $1,000 purchases per month, 2 percent on second $1,000 per month, and 3 percent on all over that.

(b) Packer's duty to inform—The packer should take reasonable action, in good faith, to inform all its competing customers of the availability of its promotional program. Such notification should include all the relevant details of the offer in time to enable customers to make an informed judgment whether to participate. Where such one-step notification is impracticable, the packer may, in lieu thereof, maintain a continuing program of first notifying all competing customers of the types of promotions offered by the packer and a specific source for the customer to contact in order to receive full and timely notice of all relevant details of the packer's promotions. Such notice should also inform all competing customers that the packer offers advertising allowances and/or other promotional assistance that are usable in a practical business sense by all retailers regardless of size. When a customer indicates its desire to be put on the notification list, the packer should keep that customer advised of all promotions available in its area as long as the customer so desires. The packer may make the required notification by any means it chooses; but in order to show later that it gave notice to a certain customer, it is in a better position to do so if it was given in writing or a record was prepared at the time of notification showing date, person notified, and contents of notification.

If more direct methods of notification are impracticable, a packer may employ one or more of the following methods, the sufficiency of which will depend upon the complexity of its own distribution system. Different packers may find that different notification methods are most effective for them:

(1) The packer may enter into contracts with its wholesaler, distributors or other third parties which conform to the requirements of item 5, infra.

(2) The packer may place appropriate announcements on product containers or inside thereof with conspicuous notice of such enclosure on the outside.

(3) The packer may publish notice of the availability and essential features of a promotional plan in a publication of general distribution in the trade.

Example 1: A packer has a wholesaler-oriented plan directed to wholesalers distributing its products to retailing customers. It should notify all the competing wholesalers distributing its products of the availability of this plan, but the packer is not required to notify retailing customers.

Example 2: A packer who sells on a direct basis to some retailers in an area, and to other retailers in the area through wholesalers, has a plan for the promotion of its products at the retail level. If the packer directly notifies not only all competing direct purchasing retailers but also all competing retailers purchasing through the wholesalers as to the availability, terms and conditions of the plan, the packer is not required to notify its wholesalers.

Example 3: A packer regularly engages in promotional programs and the competing customers include large direct purchasing retailers and smaller customers who purchase through wholesalers. The packer may encourage, but not coerce, the retailer purchasing through a wholesaler to designate a wholesaler as its agent for receiving notice of, collecting, and using promotional allowances for the customer. If a wholesaler or other intermediary by written agreement with a retailer is actually authorized to collect promotional payments from suppliers, the packer may assume that notice of and

payment under a promotional plan to such wholesaler or intermediary constitutes notice and payment to the retailer.

(A packer should not rely on a written agreement authorizing an intermediary to receive notice of and/or payment under a promotional plan for a retailer if the packer knows, or should know, that the retailer was coerced into signing the agreement. In addition, a packer should assume that an intermediary is not authorized to receive notice of and/or payment under a promotional plan for a retailer unless there is a written authorization signed by such retailer.)

(c) Availability to all competing customers—The plan should be such that all types of competing customers may participate. It should not be tailored to favor or discriminate against a particular customer or class of customers but should, in its terms, be usable in a practical business sense by all competing customers. This may require offering all such customers more than one way to participate in the plan or offering alternative terms and conditions to customers for whom the basic plan is not usable and suitable. The packer should not, either expressly or by the way the plan operates, eliminate some competing customers, although it may offer alternative plans designed for different customer classes. If it offers alternative plans, all of the plans offered should provide the same proportionate equality and the packer should inform competing customers of the various alternative plans.

When a packer, in good faith, offers a basic plan, including alternatives, which is reasonably fair and nondiscriminatory and refrains from taking any steps which would prevent any customer, or class of customers, from participating in its program, it shall be deemed to have satisfied its obligation to make its plan functionally available to all customers, and the failure of any customer or customers to participate in the program shall not be deemed to place the packer in violation of the provisions of the Packers and Stockyards Act.

Example 1: A packer offers a plan of short term store displays of varying sizes, including some which are suitable for each of its competing customers and at the same time are small enough so that each customer may make use of the promotion in a practical business sense. The plan also calls for uniform, reasonable certification of performance by the retailer. Because they are reluctant to process a reasonable amount of paperwork, some small retailers do not participate. This fact is not deemed to place a packer in violation of Item 3(c) and it is under no obligation to provide additional alternatives.

Example 2: A packer offers a plan for cooperative advertising on radio, television, or in newspapers of general circulation.[1] Because the purchases of some of its customers are too small, this offer is not ''functionally available'' to them. The packer should offer them alternative(s) on proportionally equal terms that are usable by them and suitable for their business.

(d) Need to understand terms—In informing customers of the details of a plan, the packer should provide them sufficient information to give a clear understanding of the exact terms of the offer, including all alternatives, and the conditions upon which payment will be made or services furnished.

(e) Checking customer's use of payments—The packer should take reasonable precautions to see that services it is paying for are furnished and also that it is not overpaying for them. Moreover, the customer should expend the allowance solely for the purpose for which it was given. If the packer knows or should know that what it pays or furnishes is not being properly used by some customers, the improper payments or services should be discontinued.[2]

A packer who, in good faith, takes reasonable and prudent measures to verify the performance of its competing customers will be deemed to have satisfied its obligations under the Act. Also, a packer who, in good faith, concludes a promotional agreement with wholesalers or other intermediaries and who otherwise conforms to the standards of Item 5 shall be deemed to have satisfied this obligation. If a packer has taken such steps, the fact that a particular customer has retained an allowance in excess of the cost, or approximate cost if the actual cost is not known, of services performed by the customer shall not alone be deemed to place a packer in violation of the Act.

(When customers may have different but closely related costs in furnishing services that are difficult to determine such as the cost for distributing coupons from a bulletin board or using a window banner, the packer may furnish to each customer the same payment if it has a reasonable relationship to the cost of providing the service or is not grossly in excess thereof.)

[1] In order to avoid the tailoring of promotional programs that discriminate against particular customers or class of customers, the packer in offering to pay allowances for newspaper advertising should offer to pay the same percentage of the cost of newspaper advertising for all competing customers in a newspaper of the customer's choice, or at least in those newspapers that meet the requirements for second class mail privileges.

[2] The granting of allowances or payments that have little or no relationship to cost or approximate cost of the service provided by the retailer may be considered a violation of section 202 of the Act.

4. *Competing customers.* The packer is required to provide in its plan only for those customers who compete with each other in the resale of the packer's products of like grade and quality. Therefore a packer should make available to all competing wholesalers any plan providing promotional payments or services to wholesalers, and similarly should make available to all competing retailers any plan providing promotional payments or services to retailers. With these requirements met, a packer can limit the area of its promotion. However, this section is not intended to deal with the question of a packer's liability for use of an area promotion where the effect may be to injure the packer's competition.

5. *Wholesaler or third party performance of packer's obligations.* A packer may, in good faith, enter into written agreements with intermediaries, such as wholesalers, distributors or other third parties, including promoters of tripartite promotional plans, which provide that such intermediaries will perform all or part of the packer's obligations under this part. However, the interposition of intermediaries between the packer and its customers does not relieve the packer of its ultimate responsibility of compliance with the provisions of the Packers and Stockyards Act. The packer, in order to demonstrate its good faith effort to discharge its obligations under this part, should include in any such agreement provisions that the intermediary will:

(1) Give notice to the packer's customers in conformity with the standards set forth in items 3(b) and (d), supra;

(2) Check customer performance in conformity with the standards set forth in item 3(e), supra;

(3) Implement the plan in a manner which will insure its functional availability to the packer's customers in conformity with the standards set forth in item 3(c), supra (This must be done whether the plan is one devised by the packer itself or by the intermediary for use by the packer's customers.); and

(4) Provide certification in writing and at reasonable intervals that the packer's customers have been and are being treated in conformity with the agreement.

A packer who negotiates such agreements with its wholesalers, distributors or third party promoters will be considered by the Administration to have justified its ''good faith'' obligations under this section only if it accompanies such agreements with the following supplementary measures: At regular intervals the packer takes affirmative steps to verify that its customers are receiving the proportionally equal treatment to which they are entitled by making spot checks designed to reach a representative cross section of its customers. Whenever such spot checks indicate that the agreements are not being implemented in such a way that its customers are receiving such proportionally equal treatment, the packer takes immediate steps to expand or to supplement such agreements in a manner reasonably designed to eliminate the repetition or continuation of any such discriminations in the future.

Intermediaries, subject to the Packers and Stockyards Act, administering promotional assistance programs on behalf of a packer may be in violation of the provisions of the Packers and Stockyards Act, if they have agreed to perform the packer's obligations under the Act with respect to a program which they have represented to be usable and suitable for all the packer's competing customers if it should later develop that the program was not offered to all or, if offered, was not usable or suitable, or was otherwise administered in a discriminatory manner.

6. *Customer's liability.* A customer, subject to the Packers and Stockyards Act, who knows, or should know, that it is receiving payments or services which are not available on proportionally equal terms to its competitors engaged in the resale of the same packer's products may be in violation of the provisions of the Act. Also, customers (subject to the Packers and Stockyards Act) that make unauthorized deductions from purchase invoices for alleged advertising or other promotional allowances may be proceeded against under the provisions of the Act.

Example: A customer subject to the Act should not induce or receive an allowance in excess of that offered in the packer's advertising plan by billing the packer at ''vendor rates'' or for any other amount in excess of that authorized in the packer's promotion program.

7. *Meeting competition.* A packer charged with discrimination under the provisions of the Packers and Stockyards Act may defend its actions by showing that the payments were made or the services were furnished in good faith to meet equally high payments made by a competing packer to the particular customer, or to meet equivalent services furnished by a competing packer to the particular customer. This defense, however, is subject to important limitations. For instance, it is insufficient to defend solely on the basis that competition in a particular market is very keen, requiring that special allowances be given to some customers if a packer is ''to be competitive.''

8. *Cost justification.* It is no defense to a charge of unlawful discrimination in the payment of an allowance or the furnishing of a service for a packer to show that such payment or service could be justified through

savings in the cost of manufacture, sale, or delivery.

(Approved by the Office of Management and Budget under control number 0580–0015)

[58 FR 52886, Oct. 13, 1993; 58 FR 58902, Nov. 4, 1993, as amended at 68 FR 75388, Dec. 31, 2003]

§ 203.15 Trust benefits under sections 206 and 207 of the Act.

(a) Within the times specified under sections 206(b) and 207(d) of the Act, any livestock seller, live poultry seller or grower, to preserve his interest in the statutory trust, must give written notice to the appropriate packer or live poultry dealer and file such notice with the Secretary. One of the ways to satisfy the notification requirement under these provisions is to make certain that notice is given to the packer or live poultry dealer within the prescribed time by letter, mailgram, or telegram stating:

(1) Notification to preserve trust benefits:

(2) Identification of packer or live poultry dealer;

(3) Identification of seller or poultry grower;

(4) Date of the transaction;

(5) Date of seller's or poultry grower's receipt of notice that payment instrument has been dishonored (if applicable); and

(6) Amount of money due; and to make certain that a copy of such letter, mailgram, or telegram is filed with a GIPSA Regional Office or with GIPSA, USDA, Washington, DC 20250, within the prescribed time.

(b) While the above information is desirable, any written notice which informs the packer or live poultry dealer and the Secretary that the packer or live poultry dealer has failed to pay is sufficient to meet the above-mentioned statutory requirement if it is given within the prescribed time.

(Approved by the Office of Management and Budget under control number 0580–0015)

[54 FR 16357, Apr. 24, 1989, as amended at 68 FR 75388, Dec. 31, 2003]

§ 203.16 Mailing of checks in payment for livestock purchased for slaughter, for cash and not on credit.

(a) The Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) recognizes that one who sells livestock to a packer, market agency, or dealer, who is purchasing for slaughter, may not intend to be present at the point of transfer of possession of the livestock, to receive payment, at the time a check in payment for such livestock may be delivered by the purchaser, and may not wish to authorize a representative to receive such a check; or for other reasons such a seller may prefer that such a purchaser make payment by mailing a check within the time limit as prescribed in section 409(a) of the Act. In cases when the seller does not intend to be present, he may use the following form of notification to the purchaser:

I do not intend to be present at the point of transfer of possession of livestock sold by me to (name of packer, market agency, or dealer) for the purpose of receiving a check in payment for such livestock.

I hereby direct (name of packer, market agency, or dealer) to make payment for livestock purchased from me, by mailing a check for the full amount of the purchase price before the close of the next business day following the purchase of livestock and transfer of possession thereof or, in the case of a purchase on a ''carcass'' or ''grade and yield'' basis, not later than the close of the first business day following determination of the purchase price.

This does not constitute an extension of credit to (name of packer, market agency or dealer). This is subject to cancellation by me at any time, and if not cancelled by (date), it shall terminate on that date.

If the seller, for reasons other than not being present to receive payment, prefers to have the packer, market agency, or dealer make payment by mailing a check within the time limit as provided in section 409(a), he may use the above form but should not include the statement in the first sentence that he does not intend to be present.

(b) The Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) believes that such an agreement would not constitute an extension of credit within the meaning of section 206 of the Act because it would not give the purchaser

any more time to issue a check than is provided in section 409(a).

(Approved by the Office of Management and Budget under control number 0580–0015)

(Sec. 401, 42 Stat. 168 (7 U.S.C 221); sec. 407, 42 Stat. 169 (7 U.S.C. 228); sec. 409, as added by sec. 7, 90 Stat. 1250 (7 U.S.C. 228b); 7 CFR 2.17, 2.54; 42 FR 35625; Pub. L. 96–511, 94 Stat. 2812 (44 U.S.C. 3501 *et seq.*); 7 U.S.C. 222 and 228 and 15 U.S.C. 46)

[42 FR 49929, Sept. 28, 1977, as amended at 49 FR 39516, Oct. 9, 1984; 68 FR 75388, Dec. 31, 2003]

§ 203.17 Statement of general policy with respect to rates and charges at posted stockyards.

(a) Requests have been received from stockyard operators, market agencies, and livestock producers urging a reduction of rate regulation at posted stockyards. Their requests are based on the belief that competition among markets will set a level of rates and charges fair to both the market operator and to the livestock producer. Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) will accept for filing tariffs containing any level of charges after 10 days' notice to the public and to the Secretary as required by the Act.

(b) Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) will not investigate the level of rates and charges established by stockyard owners and market agencies for reasonableness except upon receipt of a valid complaint or under compelling circumstances warranting such an investigation. Stockyard owners and market agencies will have substantial flexibility in setting their own rates and charges.

(c) Complaints filed about the reasonableness of rates and charges will be investigated to determine the validity of such complaints and appropriate action taken if warranted.

(d) Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) will continue to insure that the schedules of rates and charges filed with the Department are applied uniformly and in a nondiscriminatory manner.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 203, 204, 207, 217a, 222 and 228)

[49 FR 33004, Aug. 20, 1984, as amended at 68 FR 75388, Dec. 31, 2003]

§ 203.18 Statement with respect to packers engaging in the business of custom feeding livestock.

(a) In its administration of the Packers and Stockyards Act, the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) has sought to promote and maintain open and fair competition in the livestock and packing industries, and to prevent unfair or anticompetitive practices when they are found to exist. It is the opinion of the Administration that the ownership or operation of custom feedlots by packers presents problems which may, under some circumstances, result in violations of the Packers and Stockyards Act.

(b) Packers contemplating entering into such arrangements with custom feedlots are encouraged to consult with the Administration prior to the commencement of such activities. Custom feedlots are not only places of production, but are also important marketing centers, and in connection with the operation of a custom feedlot, it is customary for the feedlot operator to assume responsibility for marketing fed livestock for the accounts of feedlot customers. When a custom feedlot is owned or operated by a packer, and when such packer purchases fed livestock from the feedlot, this method of operation potentially gives rise to a conflict of interest. In such situations, the packer's interest in the fed livestock as a buyer is in conflict with its obligations to feedlot customers to market their livestock to the customer's best advantage. Under these circumstances, the packer should take appropriate measures to eliminate any conflict of interest. At a minimum, such measures should insure:

(1) That feedlot customers are fully advised of the common ties between the feedlot and the packer, and of their

rights and options with respect to the marketing of their livestock;

(2) That all feedlot customers are treated equally by the packer/custom feedlot in connection with the marketing of fed livestock; and

(3) That marketing decisions rest solely with the feedlot customer unless otherwise expressly agreed.

(c) Packer ownership or operation of custom feedlots may also give rise to competitive problems in some situations. Packers contemplating or engaging in the business of operating a custom feedlot should carefully review their operations to assure that no restriction of competition exists or is likely to occur.

(d) The Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) does not consider the existence of packer/custom feedlot relationships, by itself, to constitute a violation of the Act. In the event it appears that a packer/custom feedlot arrangement gives rise to a violation of the Act, an investigation will be made on a case-by-case basis, and, where warranted, appropriate action will be taken.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 203, 204, 207, 217a, 222 and 228)

[49 FR 33004, Aug. 20, 1984, as amended at 68 FR 75388, Dec. 31, 2003]

§ 203.19 Statement with respect to packers engaging in the business of livestock dealers or buying agencies.

(a) In its administration of the Packers and Stockyards Act, the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) has sought to prevent conflicts of interest and to maintain open and fair competition in the livestock and meat packing industries. The ownership or operation of livestock dealers or buying agencies by packers, under some circumstances, may result in violations of the Packers and Stockyards Act.

(b) Traditionally, livestock dealers and buying agencies purchase livestock for resale or to fill orders for farmers, ranchers, producers, other livestock firms and packers. When a livestock dealer or buying agency is owned or operated by a packer, and when such packer is also buying livestock for its own operational requirements, there is a potential conflict of interest. Furthermore, the purchase and sale of livestock by meat packers may result in control of markets and prices which could adversely affect both livestock producers, competing packers, and consumers.

(c) Arrangements between packers and dealers or buying agencies which do not normally create a conflict of interest or result in a restraint of competition include:

(1) Operations utilizing different species or classes of livestock; (2) operations where the business activities are widely separated geographically; and (3) operations where tie-in purchases or sales are not involved. Packers contemplating engaging in the business of a livestock dealer or a buying agency are encouraged to consult with the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) prior to the commencement of such activities.

(d) In the event a packer/dealer or a packer/buying agency arrangement appears to give rise to a violation of the Act, an investigation will be made on a case-by-case basis and, where warranted, appropriate action will be taken.

(Approved by the Office of Management and Budget under control number 0580–0015)

(7 U.S.C. 228, 228b, 222, 15 U.S.C. 46)

[49 FR 32845, Aug. 17, 1984; 54 FR 26349, June 23, 1989, as amended at 68 FR 75388, Dec. 31, 2003]

PART 204—ORGANIZATION AND FUNCTIONS

PUBLIC INFORMATION

Sec.

AUTHORITY: 5 U.S.C. 552.

SOURCE: 49 FR 46528, Nov. 27, 1984, unless otherwise noted.

PUBLIC INFORMATION

§ 204.1 Introduction.

The Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) hereby describes its central and field organization; indicates the established places at which, and methods whereby, the public may secure information; directs attention to the general course and method by which its functions are channeled; and sets forth the procedures governing the availability of opinions, orders, and other records in the files of said Administration.

§ 204.2 Organization.

(a) The Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) consists of a headquarters office located in the South Building of the U.S. Department of Agriculture in Washington, DC, and 12 regional offices. The Washington headquarters office is organized to include the Office of the Administrator and two Divisions, the Packer and Poultry Division and the Livestock Marketing Division.

(b) *Office of the Administrator*. This office has overall responsibility for administering the provisions of the Packers and Stockyards Act, 1921, as amended and supplemented (7 U.S.C. 181 *et seq.*), for enforcement of the Truth-in-Lending Act (15 U.S.C. 1601–1665) with respect to any activities subject to the Packers and Stockyards Act and for executing assigned civil defense and defense mobilization activities. These responsibilities include formulation of current and long-range programs relating to assigned functions; execution of the policies and programs administered by the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs); review and evaluation of program operations for uniform, effective, and efficient administration of the Packers and Stockyards Act; and maintenance of relations and communications with producer and industry groups.

(1) *Administrator*. The Secretary of Agriculture has delegated responsibility for administration of the Packers and Stockyards Act to the Administrator who is responsible for the general direction and supervision of programs and activities assigned to the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) except such activities as are reserved to the Judicial Officer (32 FR 7468). The Administrator reports to the Assistant Secretary for Marketing and Inspection Services.

(2) *Deputy Administrator*. The Deputy Administrator assists the Administrator in the overall responsibility for the general direction and supervision of programs and activities assigned to the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs).

(3) *Assistant to the Administrator*. The Assistant to the Administrator participates with the Administrator and Deputy Administrator in the development and analysis of policies and programs, and directs the management support services and related activities of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs).

(4) *Director, Industry Analysis Staff*. The Director of the Industry Analysis Staff participates with the Administrator and Deputy Administrator in the development and analysis of policies and programs and directs economic studies of structure and performance of the livestock, meat, and poultry marketing, processing, and wholesaling industries. The results of these studies are used to provide economic advice to the Administrator in developing overall policy on antitrust matters and effects of practices or impediments in the marketing system. The Director works closely with the Directors of the Packer and Poultry and the Livestock Marketing Divisions in connection with investigations to provide economic advice and expert testimony in trials and administrative hearings. The Director also coordinates activities and works closely with the Federal Trade Commission and Justice Department in studying the effects of mergers and antitrust matters in the livestock, meat packing and poultry industries.

(c) *Packer and Poultry Division*. This Division carries out the enforcement of the provisions of the Packers and

Stockyards Act relating to packers and live poultry dealers and handlers. The responsibilities and functions include: Determination of applicability of the provisions of the Act to individual packer and poultry operations; surveillance of these operations; investigation of complaints; initiation of formal proceedings, when warranted, to correct illegal practices; and maintenance of working relationships with the meat packer and poultry industries. These responsibilities and functions are accomplished with programs and activities directed through the Livestock Procurement Branch, Meat Merchandising Branch, and Poultry Branch. The Division Director participates with the Administrator and Deputy Administrator in the development and evaluation of policies and programs to fulfill the Agency's responsibilities and functions. The Director implements and directs the policies and programs pertaining to the Packer and Poultry Division through the three branches.

(d) *Livestock Marketing Division.* This Division enforces those provisions of the Packers and Stockyards Act relating to stockyard owners, market agencies, and dealers. The responsibilities and functions include: determination of the applicability of the jurisdiction, bonding, financial and trade practice provisions of the Act to individual operations; supervision of the installation, maintenance, and testing of scales; surveillance and investigations of stockyards, market agencies, and dealers; initiation of formal proceedings, when warranted, to correct illegal practices; and maintenance of working relationships with producer and industry groups. These responsibilities and functions are accomplished with programs and activities directed through the Financial Protection Branch, Marketing Practices Branch, and Scales and Weighing Branch. The Division Director participates with the Administrator and Deputy Administrator in the development and evaluation of policies and programs to fulfill the Agency's responsibilities and functions. The Director implements and directs the policies and programs pertaining to the Livestock Marketing Division through the three branches.

(e) *Field Services.* (1) The field services of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) is divided into 12 regional offices. These offices are responsible for supervision of operations of stockyard companies, market agencies, dealers, packers and live poultry dealers and handlers to assure compliance with the Act. They formulate recommendations relating to the enforcement of the Act; receive and investigate complaints, including reparation complaints; audit books, records, and reports of persons subject to the Act; conduct investigations to determine the existence of and develop evidence of unfair, deceptive, and discriminatory trade practices; prepare investigative reports and recommend corrective action; assist in the prosecution of cases; review applications for registration and rate changes for accuracy and compliance; and maintain relationships with producers, the trade, States and other groups interested in the welfare of the livestock, meat packing, and poultry industries concerning enforcement of the Act.

(2) The addresses and the States covered by these offices, which are under regional supervisors, are as follows:

Atlanta—Room 338, 1720 Peachtree Street, NW., Atlanta, Georgia 30309 (Alabama, Florida, Georgia, South Carolina)

Bedford—Turnpike Road, Box 101E, Bedford, Virginia 25423 (District of Columbia, Delaware, Maryland, North Carolina, Virginia, West Virginia)

Denver—208 Livestock Exchange Building, Denver, Colorado 80216 (Colorado, Montana, New Mexico, Utah, Wyoming)

Fort Worth—Room 8A36, Federal Building, 819 Taylor Street, Fort Worth, Texas 76102 (Oklahoma, Texas)

Indianapolis—Room 434 Federal Building and U.S. Courthouse, 46 E. Ohio Street, Indianapolis, Indiana 46204 (Illinois, Indiana, Kentucky, Michigan, Ohio)

Kansas City—828 Livestock Exchange Building, Kansas City, Missouri 64102 (Kansas, Missouri)

Lawndale—15000 Aviation Boulevard, Room 2W6, P.O. Box 6102, Lawndale, California 90261 (Arizona, California, Hawaii, Nevada)

Memphis—Room 459, Federal Building, 167 Main Street, Memphis, Tennessee 38103 (Arkansas, Louisiana, Mississippi, Tennessee)

North Brunswick—825 Georges Road, Room 303, North Brunswick, New Jersey 08902 (Connecticut, Maine, Massachusetts, New

Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont)
Omaha—909 Livestock Exchange Building, Omaha, Nebraska 68107 (Iowa, Nebraska)
Portland—9370 S.W. Greenburg Road, Suite E, Portland, Oregon 97223 (Alaska, Idaho, Oregon, Washington)
South St. Paul—208 Post Office Building, Box 8, South St. Paul, Minnesota 55075 (Minnesota, North Dakota, South Dakota, Wisconsin)

§ 204.3 Delegation of authority.

(a) *Deputy Administrator.* Under the direction of the Administrator, the Deputy Administrator is hereby delegated authority to perform all the duties and exercise all the functions and powers which are now or which may hereafter be, vested in the Administrator (including the power of redelegation).

(b) *Division Directors.* The Directors of the Industry Analysis Staff, the Livestock Marketing Division, and the Packer and Poultry Division, under administrative and technical direction of the Administrator and the Deputy Administrator, are hereby individually delegated authority, in connection with the respective functions assigned to each of said organizational units in § 204.2 to perform all the duties and to exercise all the functions and powers which are now, or which may hereafter be, vested in the Administrator (including the power of redelegation) except such authority as is reserved to the Administrator and Deputy Administrator under paragraph (g) of this section.

(c) *Regional Supervisors.* (1) The Regional Supervisors of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) are hereby individually delegated authority under the provisions of section 402 of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 222), to issue special orders pursuant to the provisions of section 6(b) of the Federal Trade Commission Act (15 U.S.C. 46(b)), and, with respect thereto, to issue notices of default provided for in section 10 of the Federal Trade Commission Act (15 U.S.C. 50); to notify persons deemed to be subject to the bonding requirements in 7 U.S.C. 204 of their obligations to file bonds or trust fund agreements in conformity with regulations issued under this chapter including authority to determine that a bond is inadequate under § 201.30(f) of this chapter and to give notice to the person of the amount of bond required; to notify persons deemed to be subject to the reporting requirements in § 201.97 of this chapter of their obligations to file annual reports; and to grant reasonable requests for extensions of 30 days or less for the filing of such annual reports.

(2) The Regional Supervisors are hereby individually delegated authority, when there is reason to believe that there is a question as to the true ownership of livestock sold by any person, to disclose information relating to such questionable ownership to any interested person.

(d) *Investigative employees.* All employees of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) assigned to or responsible for investigations in the enforcement of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*), or the enforcement of the Truth-in-Lending Act (15 U.S.C. 1601–1665), with respect to any activities subject to the Packers and Stockyards Act, are hereby individually delegated authority under the Act of January 31, 1925, 43 Stat. 803, 7 U.S.C. 2217, to administer to or take from any person an oath, affirmation, or affidavit whenever such oath, affirmation, or affidavit is for use in any prosecution or proceeding under or in the enforcement of the aforementioned Acts. This authority may not be redelegated and will automatically expire upon the termination of the employment of such employees with the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs).

(e) *Concurrent authority.* No delegation prescribed herein shall preclude the Administrator or Deputy Administrator from exercising any of the powers or functions or from performing any of the duties conferred upon them, and any such delegation is subject at all times to withdrawal or amendment by the Administrator or Deputy Administrator or the Division Director responsible for the function involved.

(f) *Prior delegations.* All prior delegations and redelegations of authority relating to any function or activity covered by these delegations of authority shall remain in effect except as they are inconsistent herewith or are hereafter amended or revoked. Nothing herein shall affect the validity of any action heretofore taken under prior delegations or redelegations of authority or assignment of functions.

(g) *Reservations of authority.* It is hereby reserved to the Administrator and Deputy Administrator authority with respect to proposed rulemaking and final action for the issuance of regulations (§ 201.1 of this chapter *et seq.*), rules of practice governing proceedings (§ 202.1 of this chapter *et seq.*), and statements of general policy (§ 203.1 of this chapter *et seq.*), and the issuance of moving papers as prescribed in the rules of practice governing formal adjudicatory administrative proceedings instituted by the Secretary (7 CFR part 1, subpart H, § 1.133); and the authority to make final determinations in accordance with the provisions of 7 CFR part 1, subpart A, as to the availability of official records and information made or obtained in connection with the administration of the Packers and Stockyards Act which are considered exempt from disclosure under § 204.7 of this part. Further, authority to issue subpoenas (7 U.S.C. 222 and 15 U.S.C. 49) is reserved to the Administrator and Deputy Administrator.

§ 204.4 Public inspection and copying.

(a) Facilities for public inspection and copying of the indexes and materials required to be made available under 7 CFR 1.2(a) will be provided by the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) during normal hours of operation. Requests for this information should be made to the Freedom of Information Act Officer, Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs, United States Department of Agriculture, Washington, DC 20250.

(b) Copies of such materials may be obtained in person or by mail. Applicable fees for copies will be charged in accordance with the regulations prescribed by the Director of Information, Office of Governmental and Public Affairs, USDA.

§ 204.5 Indexes.

Pursuant to the regulations in 7 CFR 1.4(b), the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs) will maintain and make available for public inspection and copying current indexes of all material required to be made available in 7 CFR 1.2(a). Notice is hereby given that publication of these indexes is unnecessary and impractical, since the material is voluminous and does not change often enough to justify the expense of publication.

§ 204.6 Requests for records.

(a) Requests for records under 5 U.S.C. 552(a)(3) shall be made in accordance with 7 CFR 1.3(a). Authority to make determinations regarding initial requests in accordance with 7 CFR 1.4(c) is delegated to the Freedom of Information Act Officer of the Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs). Requests should be submitted to the FOIA Officer at the following address: Freedom of Information Act Officer (FOIA Request), Grain Inspection, Packers and Stockyards Administration (Packers and Stockyards Programs), United States Department of Agriculture, Washington, DC 20250.

(b) The request shall identify each record with reasonable specificity as prescribed in 7 CFR 1.3.

(c) The FOIA Officer is authorized to receive requests and to exercise the authority to (1) make determination to grant requests or deny initial requests; (2) extend the administrative deadline; (3) make discretionary release of exempt records; and (4) make determinations regarding charges pursuant to the fee schedule.

§ 204.7 Appeals.

Any person whose request under § 204.6 of this part is denied shall have the right to appeal such denial in accordance with 7 CFR 1.3(e). Appeals shall be addressed to the Administrator, Grain Inspection, Packers and Stockyards Administration (Packers

and Stockyards Programs), U.S. Department of Agriculture, Washington, DC 20250.

PART 205—CLEAR TITLE—PROTECTION FOR PURCHASERS OF FARM PRODUCTS

DEFINITIONS

REGULATIONS

INTERPRETIVE OPINIONS

AUTHORITY: 7 U.S.C. 1631; 7 CFR 2.22 and 2.81.

SOURCE: 51 FR 29451, Aug. 18, 1986, unless otherwise noted.

DEFINITIONS

§ 205.1 Definitions.

Terms defined in section 1324 of the Food Security Act of 1985, Pub. L. 99–198, 99 Stat. 1535, 7 U.S.C. 1631, shall mean the same in this part as therein. In addition, except as otherwise specified, as used in this part:

Approved Unique Identifier means a combination of numbers selected by the Secretary of State using a selection system or method approved by the Secretary of Agriculture.

EFS means *effective financing statement* as defined in subsection (c)(4);

Master list means the accumulation of data in paper, electronic, or other form, described in subsection (c)(2)(C);

Portion means portion of the master list distributed to registrants under subsection (c)(2)(E);

Registrant means any buyer of farm products, commission merchant, or selling agent, as referred-to in the Section, registered with a system under subsection (c)(2)(D);

The Secretary means the Secretary of Agriculture of the United States;

The Section means section 1324 of the above-cited Act, and ''subsection'' means a subsection of that Section;

System means *central filing system* as defined in subsection (c)(2);

System operator means Secretary of State or other person designated by a State to operate a system;

UCC or *Uniform Commercial Code* means the Uniform Commercial Code prepared under the joint sponsorship of the American Law Institute and the National Conference of Commissioners on Uniform State Laws, and in effect in most States of the United States at the time of enactment of Pub. L. 99–198.

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56342, Sept. 27, 2006; 72 FR 25948, May 8, 2007]

REGULATIONS

§ 205.101 Certification—request and processing.

(a) To obtain certification of a system, a written request for certification must be filed together with such documents as show that the system complies with the Section. If such material is voluminous, a summary, table of contents, and index must accompany it as necessary to facilitate review.

(b) The request must:

(1) Include an introductory explanation of how the system will operate;

(2) Identify the information which will be required to be supplied on an EFS;

(3) Identify where an EFS, amendment thereto, or continuation thereof, will be filed and, if elsewhere than with the system operator, explain how and in what form the system operator will receive information needed to compile and update the master list;

(4) Explain the method for recording the date and hour of filing of an EFS, amendment thereto, or continuation thereof;

(5) Explain how the master list will be compiled, including the method and form of storage and arrangement of information, explain the method and form of retrieval of information from the master list, the method and form of distribution of portions of the master list to registrants as required by subsection (c)(2)(E), and the method and form of furnishing of information orally with written confirmation as required by subsection (c)(2)(F) (details of computer hardware and software need not be furnished but the results it will produce must be explained);

(6) Explain how the list of registrants will be compiled, including identification of where and how they will register, what information they must supply in connection with registration, and the method and form of storage and retrieval of such information (details of computer hardware and software need not be furnished but the results it will produce must be explained);

(7) Show how frequently portions of the master list will be distributed regularly to registrants;

(8) Show the farm products according to which the master list will be organized;

(9) Show how the system will interpret the term ''crop year'' and how it will classify as to crop year an EFS not showing crop year;

(10) Show what fee will be charged and explain how the costs of the system will be covered if not by such fee and the general revenue of the State;

(11) If a unique identifier will be used in the system, explain how the unique identifier will be selected and how it will be used by the system, including, but not limited to, how lists will be organized, and how searches may be performed, using the unique identifier.

(12) Include copies of:

(i) All State legislation or other legal authority under which the system is created and operated, and the system operator is designated;

(ii) All regulations, rules, and requirements issued under such legislation or other legal authority and governing operation of the system, designation of the system operator, and use of the system by members of the public; and

(iii) All printed and electronic forms required to be used in connection with the system.

(c) Any such request and attachments must be filed in triplicate (one copy for public inspection, a second copy for use in GIPSA, and a third copy for use in the Office of the General Counsel, USDA). All three copies must be received in the headquarters of thePackers and Stockyards Program, Grain Inspection, Packers and Stockyards Administration (GIPSA), USDA, Washington, DC 20250.

(d) A refusal to certify such a system, if any, will be explained in writing. Reconsideration of such a refusal must be requested in writing with specification of errors believed to have been made.

(e) To make changes to an existing certified central filing system, including changes necessitated or made possible by amendments to the Section, a written request to amend the existing certified central filing system must be filed together with such documents as are necessary to show that the system complies with the Section. The request must contain relevant new information consistent with the requirements specified elsewhere in this section.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 61 FR 54728, Oct. 22, 1996; 71 FR 56342, Sept. 27, 2006]

§ 205.102 Name of person subjecting a farm product to a security interest, on EFS and master list—format.

On an EFS, and on a master list, the name of the person subjecting a farm product to a security interest must appear as follows:

(a) In the case of a natural person, the surname (last name or family name) must appear first;

(b) In the case of a corporation or other entity not a natural person, the name must appear beginning with the first word or character not an article or punctuation mark.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56342, Sept. 27, 2006]

§ 205.103 EFS—minimum information.

(a) The minimum information necessary on an EFS is as follows:

(1) Crop year *unless* every crop of the farm product in question, for the duration of the EFS, is to be subject to the particular security interest;

(2) Farm product name (see §§ 205.106, 205.206);

(3) Each county or parish in the same State where the farm product is produced or located;

(4) Name and address of each person subjecting the farm product to the security interest, whether or not a debtor (see § 205.102);

(5) Social security number or other approved unique identifier or, if other than a natural person, IRS taxpayer identification number or other approved unique identifier of each such person;

(6) Further details of the farm product subject to the security interest *if needed* to distinguish it from other such product owned by the same person or persons but not subject to the particular security interest (see § 205.207); and

(7) Secured party name and address.

(b) A requirement of additional information on an EFS is discretionary with the State.

(c) Whether to permit one EFS to reflect multiple products, or products in multiple counties, is discretionary with the State.

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[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56342, Sept. 27, 2006]

§ 205.104 Registration of buyer, commission merchant, or selling agent—minimum information.

(a) The minimum information necessary on a registration of a buyer, commission merchant, or selling agent is as follows:

(1) Buyer, commission merchant, or selling agent name and address;

(2) Farm product or products (see §§ 205.106, 205.206) in which registrant is interested; and

(3) If registrant is interested only in such product or products produced or located in a certain county or parish, or certain counties or parishes, in the same State, the name of each such county or parish.

(b) A registrant, if not registered for any specified county or parish, or counties or parishes, must be deemed to have registered for all counties and parishes shown on the master list.

(c) A requirement of additional information on a registration form is discretionary with the State.

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[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56342, Sept. 27, 2006]

§ 205.105 Master list and portion thereof distributed to registrants—format.

(a) The master list must contain all the information on all the EFS's filed in the system, so arranged that it is possible to deliver to any registrant all such information relating to any product, produced or located in any county or parish (or all counties or parishes), for any crop year, covered by the system. The system must be able to deliver all such information to any registrant, either in alphabetical order by the word appearing first in the name of each person subjecting a product to a security interest (see § 205.102), in numerical order by social security number or approved unique identifier (or, if other than a natural person, IRS taxpayer identification number or approved unique identifier) of each such person, or in both alphabetical and numerical orders, as requested by the registrant.

(b) Section (c)(2)(E) requires the portion to be distributed in ''written or printed form.'' This means recording

on paper by any technology in a form that can be read by humans without special equipment. The system may, however, honor requests from registrants to substitute recordings on any medium by any technology including, but not limited to, electronic recording on tapes or discs in machine-readable form, and on photographic recording on microfiche. It also includes, if requested by registrants, electronic transmissions whereby registrants can print their own paper copies.

(c) After distribution of a portion of a master list, there can be supplementary distribution of a portion showing only changes from the previous one. However, if this is done, cumulative supplements must be distributed often enough that readers can find all the information given to them for any one crop year in no more than three distributions.

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[51 FR 29451, Aug. 18, 1986, as amended at 61 FR 54728, Oct. 22, 1996; 71 FR 56343, Sept. 27, 2006]

§ 205.106 Farm products.

The farm products, according to which the master list must be organized as required by subsection (c)(2), and which must be identified on an EFS as required by subsection (c)(4)(C)(iv), must be specific commodities, species of livestock, and specific products of crops or livestock. The Section does not permit miscellaneous categories.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.107 Crop year.

(a) The crop year, according to which subsection (c)(2)(C)(ii)(IV) requires the master list to be arranged ''within each such product,'' must be:

(1) For a crop grown in soil, the calendar year in which it is harvested or to be harvested;

(2) For animals, the calendar year in which they are born or acquired;

(3) For poultry or eggs, the calendar year in which they are sold or to be sold.

(b) An EFS or notice thereof which does not show crop year (the Section does not require it to do so) must be regarded as applicable to the crop or product in question for every year for which subsection (c)(4)(E) makes the EFS effective.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

INTERPRETIVE OPINIONS

§ 205.201 System operator.

The system operator can be the Secretary of State of a State, or any designee of the State pursuant to its laws. Note that the provision in subsection (c)(2) for a system refers to operation by the Secretary of State of a State, but the definition in (c)(11) of ''Secretary of State'' includes ''designee of the State.''

§ 205.202 "Effective financing statement" or EFS.

(a) An EFS under subsection (c)(4) need not be the same as a financing statement or security agreement under the Uniform Commercial Code (or equivalent document under future successor State law), but can be an entirely separate document meeting the definition in (c)(4). Note that (c)(4) contains a comprehensive definition of the term which does not include any requirement that the EFS be the instrument by which a security interest is created or perfected. Note also the House Committee Report on Pub. L. 99–198, No. 99–271, Part 1, September 13, 1985, at page 110: ''[T]he bill would not preempt basic state-law rules on the creation, perfection, or priority of security interests.''

(b) An EFS may be filed electronically provided a State allows electronic filing of financing statements without the signature of the debtor under applicable State law under provisions of the Uniform Commercial Code or may be a paper document. An electronically filed EFS need not be a paper document and need not be signed. If an original or reproduced paper document of an EFS is filed with the State, it must be signed, authorized, or otherwise authenticated by the

debtor and be filed by the secured party.

(c) Countermeasures against mishandling after filing, such as a requirement that a copy be date stamped and returned to the secured party, are discretionary with the State. If a State chooses to adopt such countermeasures, it is responsible for establishing procedures for recording the date and time when an EFS is received, and for meeting all legal requirements associated with filing and distributing information about security interests as required by § 205.101.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 61 FR 54728, Oct. 22, 1996; 71 FR 56343, Sept. 27, 2006]

§ 205.203 Place of filing EFS.

The place of filing an EFS is wherever State law requires, which need not be with the system operator so long as the system operator receives the information needed for the master list, including the information required in subsection (c)(4)(C). Note that the requirements in subsection (c)(4) for an EFS include the requirement that it be ''filed with the Secretary of State,'' but the definition in (c)(11) of ''Secretary of State'' includes ''designee of the State,'' and the requirements in (c)(2) for a system refer in (A) to filing with the system operator of ''effective financing statements *or notice of such financing statements*.'' (emphasis added)

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.204 Filing "notice" of EFS.

(a) If an EFS is filed somewhere other than with the system operator, and if notice of it is filed with the system operator, such notice could be electronic filing, telephoned information, or any other form of notice which gives the system operator the information needed for the master list. Such notice need not be signed. Note that the Section does not contain any requirement for such notice except the one in subsection (c)(4)(B) that an EFS must be filed somewhere pursuant to State law as discussed above.

(b) Countermeasures against falsifications, errors or omissions in such notices or in the handling of them by the system operator, such as requirements that the notices be on paper and signed, with copies date-stamped and returned to the persons filing them, however advisable they might be from other standpoints, are discretionary with the State and not required by the Section.

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[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.205 Fees.

The Section provides at subsection (c)(4)(G) for a fee for filing an EFS. The fee can be set in any manner provided by the law of the State in which such EFS is filed. The basis for this is that (c)(4)(G) provides for the fee to be set by the ''Secretary of State'' but (c)(11) defines the latter term to include ''designee of the State.'' The fee structure is discretionary with the State.

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.206 Farm products.

(a) The master list must be organized by farm product as required by subsection (c)(2) and the farm product must be identified on an EFS as required by subsection (c)(4)(C)(iv). The following is a list of such farm products.

Rice, rye, wheat, other food grains (system must specify by name)
Barley, corn, hay, oats, sorghum grain, other feed crops (system must specify by name)
Cotton
Tobacco
Flaxseed, peanuts, soybeans, sunflower seeds, other oil crops (system must specify by name)
Dry beans, dry peas, potatoes, sweet potatoes, taro, other vegetables (system must specify by name)
Artichokes, asparagus, beans lima, beans snap, beets, Brussels sprouts, broccoli, cabbage, carrots, cauliflower, celery, corn sweet, cucumbers, eggplant, escarole, garlic, lettuce, onions, peas green, peppers, spinach, tomatoes, other truck crops (system must specify by name)
Melons (system must specify by name)

Grapefruit, lemons, limes, oranges, tangelos, tangerines, other citrus fruits (system must specify by name)
Apples, apricots, avocados, bananas, cherries, coffee, dates, figs, grapes (& raisins), nectarines, olives, papayas, peaches, pears, persimmons, pineapples, plums (& prunes), pomegranates, other noncitrus fruits (system must specify by name)
Berries (system must specify by name)
Tree nuts (system must specify by name)
Bees wax, honey, maple syrup, sugar beets, sugar cane, other sugar crops (system must specify by name)
Grass seeds, legume seeds, other seed crops (system must specify by name)
Hops, mint, popcorn, other miscellaneous crops (system must specify by name)
Greenhouse & nursery products produced on farms (system must specify by name)
Mushrooms, trees, other forest products (system must specify by name)
Chickens, ducks, eggs, geese, turkeys, other poultry or poultry products (system must specify by name)
Cattle & calves, goats, horses, hogs, mules, sheep & lambs, other livestock (system must specify by name)
Milk, other dairy products produced on farms (system must specify by name)
Wool, mohair, other miscellaneous livestock products produced on farms (system must specify by name)
Fish, shellfish
Other farm products (system must specify by name).

(b) Note the definition of the term ''farm product'' at subsection (c)(5), and the Conference Report on Pub. L. 99–198, No. 99–447, December 17, 1985, at page 486.

(c) A State may establish a system for specified products and not for all. A State establishing a system for specified products and not for all will be deemed to be ''a State that has established a central filing system'' as to the specified products, and will be deemed not to be such a State as to other products.

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[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.207 "Amount" and "County or parish".

(a) The ''amount'' of farm products and ''county or parish,'' on an EFS and on the master list under subsection (c)(4)(C)(iv) and (2)(C)(iii), need not be shown on every EFS and master list entry.

(b) Any EFS and master list entry will identify a product. If they do not show an amount, this constitutes a representation that all of such product owned by the person in question is subject to the security interest in question.

(c) Any EFS and master list entry will identify each county or parish in the same State where the product is produced or located. If they do not show any further identification of the location of the product, this constitutes a representation that all such product produced in each such county or parish, owned by such person, is subject to the security interest.

(d) The need to supply additional information arises only where some of that product owned by that person is subject to the security interest and some is not.

(e) The additional information about amount must be sufficient to enable a reader of the information to identify what product owned by that person is subject, as distinguished from what of the same product owned by the same person is not subject. The precision needed, in the description of the amount, would vary from case to case.

(f) The basis for this is the purpose of the entire exercise, to make information available as necessary to enable an identification of what product is subject to a security interest as distinguished from what is not.

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[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.208 Distribution of portions of master list—registration—information to non-registrants on request.

(a) The provisions in the Section regarding registration of ''buyers of farm products, commission merchants, and selling agents,'' ''regular'' distribution of ''portions'' of the master list, furnishing of ''oral confirmation * * * on request,'' and the effect of all this, that is, subsections (c)(2) (D), (E) and (F), (e)(2) and (3), and (g)(2) (C) and (D), must be read together.

(b) The Section does not require such persons to register. Not registering

with a particular system operator has the effect, under subsections (e)(2) and (g)(2)(C), of making such persons, whether they are inside or outside the State covered by that system, subject to security interests shown on that system's master list whether or not such persons know about them, so that such persons for their own protection will need to query the system operator about any seller ''engaged in farming operations,'' of a farm product produced in the State covered by that system, with whom they deal.

(c) The effect of registration by such persons with a particular system is to get them on the list for regular distribution of portions of that system's master list, the portions to be determined by the registration. They are subject only to security interests shown on the portions which they receive, and are not subject to such interests as are shown on the master list but not shown on portions which they receive. Also, if a particular security interest is shown on the master list, but has been placed on it since the last regular distribution of portions of that list to registrants, registrants would not be subject to that security interest. These conclusions are based on the provisions in subsections (e)(3)(A) and (g)(2)(D)(i) that such persons are subject to a security interest only if they receive ''written notice * * * that specifies both the seller and the farm product.''

(d) A question arises as to the length of time for which a registration is effective, and whether a registrant, wishing to change registration as to county or product, can amend an existing registration or must file a new one. This is discretionary with the State since the Section is silent about it.

(e) A question arises whether persons can register to receive only portions of the list for products in which they do not deal, and thus not be subject to security interests in products in which they deal because they are registrants but do not receive written notice of them. For example, can cattle dealers register to receive portions of the master list only for oranges, and thus take cattle free and clear of security interests shown on the master list, but as to which they do not receive written notice because they have not registered to receive the portion for cattle? Registrants will be deemed to be registered only *as to those portions* of the master list for which they register, and will be deemed to have failed to register as to those portions for which they do not register.

(f) The Section requires ''regular'' distribution, to registrants, of portions of the master list as amended from time to time by the filing of EFS's and amendments to EFS's. The requirement that the distribution be ''regular'' necessarily refers to an interval specified in advance. The interval may vary according to product and region. The frequency of such distribution must be a consideration in review for certification since distribution must be timely to serve its purpose. While subsection (c)(2)(E) (providing that distribution be made ''regularly as prescribed by the State'') gives each State discretion to choose the interval between distributions, whatever interval a State chooses will inevitably make possible some transactions in which security interests are filed in the system but registrants are not subject to them.

(g) Legislative history of the Section shows that buyers, commission merchants, and selling agents are not intended to be liable for errors or other inaccuracies generated by the system. See Nov. 22, 1985 Cong. Rec., Senate, pg. S16300, and Dec. 18, 1985 Cong. Rec., House, pg. H12523.

(h) In furnishing to non-registrants ''oral confirmation within 24 hours of any [EFS] on request followed by written confirmation,'' by a system operator pursuant to subsection (c)(2)(F), any failure in use of a telephone caused by a ''busy signal'' could not be the basis of liability of the system operator. The basis for this is that subsection (c)(2)(F) does not mention telephones. Also, while it mentions *furnishing* information orally, it does not contain any provision as to how queries are to be *received*, that is, orally, in writing, or otherwise.

(i) Of course it is to be expected that telephones would be used in most cases, but use of them is not required by the legislation and is discretionary with the State.

(j) In the matter of receiving queries and giving oral replies to them, subsection (c)(2)(F) will be complied with if a system operator maintains an office and staff where a query can be received on business days and during business hours such as are regular in the State, and where an oral reply will be available on the regular business day following the day on which the query is received, at or before the time of day when it was received.

(k) Written confirmation is required, by subsection (c)(2)(F), to be given to any non-registered buyer, commission merchant, or selling agent.

(l) Such a written confirmation pursuant to subsection (c)(2)(F) does not alter the liability of the non-registrant querying the system and receiving information about a security interest recorded in it. The basis of this, as above, is that non-registrants are subject to security interests recorded in a system whether or not they know about them, and must query the system for their own protection.

(m) The Section does not specify when or how the written confirmation must be furnished, but provides only that it must follow the oral information. Thus the time and method of furnishing written confirmation is discretionary with the State.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.209 Amendment or continuation of EFS.

(a) The ''material change,'' required by subsection (c)(4)(D) to be reflected in an amendment to an EFS and master list entry, is whatever change would render the master list entry no longer informative as to what is subject to the security interest in question. That will vary from case to case. The basis for this is the purpose for which the information is supplied, that is, to make information available, to a buyer, commission merchant, or selling agent who proposes to enter into a transaction in a product, whether it is subject to a security interest. The requirement to amend arises when the information already made available no longer serves the purpose and other information is needed in order to do so.

(b) Where an owner of a product makes a change, such as planting a different crop or purchasing different animals from what was represented, without informing the secured party, so that the master list entry is rendered not informative, but the EFS and master list are not amended through no fault of the secured party, the Section is silent as to the consequences. However, see the legislative history cited in § 205.208(f).

(c) The amendment must be filed in the same manner as the original filing. Note the requirement of subsection (c)(4)(D). The amendment may be filed electronically provided a State allows electronic filing of financing statements without the signature of the debtor under applicable State law under provisions of the Uniform Commercial Code. An electronically filed amendment need not be signed. However, if an original or reproduced paper document is filed, the amendment must be signed, authorized, or otherwise authenticated by the debtor, and be filed by the secured party.

(d) An effective financing statement remains effective for a period of 5 years from the date of filing and may be continued in increments of 5-year periods beyond the initial 5-year filing period by refiling an effective financing statement or by filing a continuation statement within 6 months before expiration of the effective financing statement. A continuation statement may be filed electronically or as a paper document, and need not be signed, authorized, or otherwise authenticated by the debtor.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 61 FR 54728, Oct. 22, 1996; 63 FR 66721, Dec. 3, 1998; 71 FR 56343, Sept. 27, 2006]

§ 205.210 Effect of EFS outside State in which filed.

(a) A question arises whether, if an EFS is filed in one State, a notice of it can be filed in another State and shown on the master list for the second State. There is nothing in the Section to prevent this, but it would serve no purpose.

(b) The Section provides only for filing an EFS, covering a given product, in the system for the State in which it is produced or located. Upon such filing in such system, subsections (e)(2) and (g)(2)(C) make buyers, commission merchants and selling agents *not registered* with that system subject to the security interest in that product whether or not they know about it, *even if they are outside that State*. Subsections (e)(3) and (g)(2)(D) make persons *registered* with that system subject if they receive written notice of it *even if they are outside that State*. All of these provisions apply only where an EFS is filed in the system for the State in which the product is produced or located. They do not apply to a filing in another system.

(c) What constitutes ''receipt'' of notice is determined by the law of the State in which the intended recipient of notice resides. This is based on subsection (f) which follows provisions for notice to buyers, and (g)(3) which follows provisions for notice to commission merchants and selling agents. Each of those provisions uses the word ''buyer'' but it means ''intended recipient of notice.''

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.211 Applicability of court decisions under the UCC.

(a) Court decisions under the Uniform Commercial Code (UCC), about the scope of the ''farm products'' exception in Section 9–307(1) thereof, and interpreting the terms therein, particularly ''person engaged in farming operations'' which is not defined in the Section, are applicable to an extent in interpreting the Section. The basis of this is the legislative intent of the Section to pre-empt State laws reflecting that ''farm products'' exception, as shown in the House Committee Report on Pub. L. 99–198, No. 99–271, Part 1, September 13, 1985, at pages 108 *et seq*.

(b) That UCC Section 9–307(1) reads as follows:

(1) A buyer in ordinary course of business (subsection (9) of Section 1–201) *other than a person buying farm products from a person engaged in farming operations* takes free of a security interest created by his seller even though the security interest is perfected and even though the buyer knows of its existence. (emphasis added)

§ 205.212 "Buyer in ordinary course of business" and "security interest."

The terms ''buyer in ordinary course of business'' and ''security interest'' are defined in subsections (c) (1) and (7). There are differences between those definitions and the UCC definitions of the same terms. In interpreting those differences, the following would be pertinent:

(a) The legislative intent discussed above in § 205.211, to pre-empt State laws reflecting the ''farm products'' exception; and

(b) The legislative intent shown in subsections (a) and (b) that certain persons take free and clear of certain interests of a ''secured lender'' ''when the seller fails to repay the lender,'' unless such persons have information about such interests made available to them as provided in the Section.

§ 205.213 Obligations subject—"person indebted"—"debtor."

(a) A debt need not exist at the time of filing of an EFS. The basis for this is that subsection (c)(4) does not require the EFS, and subsection (c)(2)(C) does not require the master list, to show any amount of debt.

(b) The Section does not provide for the transaction in which one person subjects a product to a security interest for another's debt. However the terms ''person indebted'' and ''debtor'' in the Section refer to the person who owns a product and subjects it to a security interest, whether or not that person owes a debt to the secured party. The basis for this is the purpose for which the information is supplied. Any buyer of a farm product, commission merchant, or selling agent querying a master list or system operator about a prospective seller of a farm product is interested in whether that seller has subjected that product to a security interest, not in whether the debt is owed by that seller or by another.

(c) Security interests existing prior to establishment of a system can be filed in such a system and reflected in the master list if documents are in existence or are created which meet the

requirements of subsection (c)(4) besides filing, if such documents are filed wherever State law requires, and if the system operator receives the information about them needed for the master list.

(d) A system can be in compliance with the Section, although it reflects security interests not supported by EFS's as defined in the legislation, and although it reflects security interests on items other than farm products. However, subsections (e) (2) and (3), and (g)(2) (C) and (D), will apply only as to entries reflecting farm products and supported by EFS's as defined in the Section, and it must be possible to distinguish the entries to which these provisions apply from the other entries.

(Approved by the Office of Management and Budget under control number 0580–0016)

[51 FR 29451, Aug. 18, 1986, as amended at 71 FR 56343, Sept. 27, 2006]

§ 205.214 Litigation as to whether a system is operating in compliance with the Section.

(a) The requirements for a system in subsection (c) are written as the definition of the term ''central filing system,'' so that failure of a system to meet any such requirement, either at the time of its establishment or later, will mean that it is not a ''central filing system'' as defined.

(b) The issue whether a system, after certification, is operating in compliance, thus whether it is a ''central filing system'' as defined, could be litigated and ruled on in a case involving only private parties, such as a lender and a buyer of a farm product. The only immediate effect of a finding in such a case, that a system is not a ''central filing system'' as defined, would be that the rights of the secured party in the case would be as if the State had no system. However, others would be in doubt as to whether they could safely rely on the same system.

PART 206—SWINE CONTRACT LIBRARY

Sec.

AUTHORITY: 7 U.S.C. 198–198b; 7 U.S.C. 222.

SOURCE: 75 FR 16642, Apr. 2, 2010, unless otherwise noted.

§ 206.1 Definitions.

The definitions in this section apply to the regulations in this part. The definitions in this section do not apply to other regulations issued under the Packers and Stockyards Act (P&S Act) or to the P&S Act as a whole.

Accrual account. (Synonymous with the term ''ledger,'' as defined in this section.) An account held by a packer on behalf of a producer that accrues a running positive or negative balance as a result of a pricing determination included in a contract that establishes a minimum and/or maximum level of base price paid. Credits and/or debits for amounts beyond these minimum and/or maximum levels are entered into the account. Further, the contract specifies how the balance in the account affects producer and packer rights and obligations under the contract.

Base price. The price paid for swine before the application of any premiums or discounts, expressed in dollars per unit.

Boar. A sexually-intact male swine.

Ceiling price. The maximum market price that will be paid for swine. Adjustments may be made to the base price if the market price rises above this price.

Contract. Any agreement, whether written or verbal, between a packer and a producer for the purchase of swine for slaughter, except a negotiated purchase (as defined in this section).

Contract type. The classification of contracts or risk management agreements for the purchase of swine committed to a packer, by the determination of the base price and the presence or absence of an accrual account or ledger (as defined in this section). The contract type categories are:

(1) Swine or pork market formula purchases with a ledger,

(2) Swine or pork market formula purchases without a ledger,

(3) Other market formula purchases with a ledger,

(4) Other market formula purchases without a ledger,

(5) Other purchase arrangements with a ledger, and

(6) Other purchase arrangements without a ledger.

Floor price. The minimum market price that will be paid for swine. Adjustments may be made to the base price if the market price falls below this price.

Formula price. A price determined by a mathematical formula under which the price established for a specified market serves as the basis for the formula.

Ledger. (Synonymous with ''accrual account,'' as defined in this section.) An account held by a packer on behalf of a producer that accrues a running positive or negative balance as a result of a pricing determination included in a contract that establishes a minimum and/or maximum level of base price paid. Credits and/or debits for amounts beyond these minimum and/or maximum levels are entered into the account. Further, the contract specifies how the balance in the account affects producer and packer rights and obligations under the contract.

Negotiated purchase. A purchase, commonly known as a ''cash'' or ''spot market'' purchase, of swine by a packer from a producer under which:

(1) The buyer-seller interaction that results in the transaction and the agreement on actual base price occur on the same day; and

(2) The swine are scheduled for delivery to the packer not later than 14 days after the date on which the swine are committed to the packer.

Noncarcass merit premium or discount. An increase or decrease in the price for the purchase of swine made available by an individual packer or packing plant, based on any factor other than the characteristics of the carcass, if the actual amount of the premium or discount is known before the purchase and delivery of the swine.

Other market formula purchase. A purchase of swine by a packer in which the pricing determination is a formula price based on any market other than the markets for swine, pork, or a pork product. This includes a formula purchase where the price formula is based on one or more futures or options contracts.

Other purchase arrangement. A purchase of swine by a packer that is not a negotiated purchase, swine or pork market formula purchase, or other market formula purchase, and does not involve packer-owned swine. This contract type includes long term contract agreements, fixed price contracts, cost of production formulas, and formula purchases with a floor, window or ceiling price.

Packer. Any person engaged in the business of buying swine in commerce for purposes of slaughter, of manufacturing or preparing meats or meat food products from swine for sale or shipment in commerce, or of marketing meats or meat food products from swine in an unmanufactured form, acting as a wholesale broker, dealer, or distributor in commerce. The regulations in this part apply only to a packer that meets the conditions in either paragraph (1) or (2) of this definition:

(1) A packer purchasing at least 100,000 swine per year and slaughtering swine at one or more federally inspected processing plants that meet either of the following conditions:

(i) A swine processing plant that slaughtered an average of at least 100,000 head of swine per year during the immediately preceding 5 calendar years, with the average based on those periods in which the plant slaughtered swine; or

(ii) A swine processing plant that did not slaughter swine during the immediately preceding 5 calendar years that has the capacity to slaughter at least 100,000 swine per year, based on plant capacity information.

(2) Any packer purchasing an average of at least 200,000 sows, boars, or any combination thereof, per year and slaughtering at least 200,000 sows, boars, or any combination thereof at one or more federally inspected processing plants during the immediately preceding 5 calendar years, with the average based on those periods in which the plant slaughtered swine.

Producer. Any person engaged, either directly or through an intermediary, in the business of selling swine to a packer for slaughter (including the sale of swine from a packer to another packer).

Sow. An adult female swine that has produced one or more litters.

Swine. A porcine animal raised to be a feeder pig, raised for seedstock, or raised for slaughter.

Swine or pork market formula purchase. A purchase of swine by a packer in which the pricing mechanism is a formula price based on a market for swine, pork, or pork product, other than any formula purchase with a floor, window or ceiling price, or a futures or option contract for swine, pork, or a pork product.

Window price. The range of market prices that will be paid for swine. Adjustments may be made to the base price if the market prices fall outside this range. The window price contains both the floor and ceiling prices.

§ 206.2 Swine contract library.

(a) *Do I need to provide swine contract information?* Each packer, as defined in § 206.1, must provide information for each swine processing plant that it operates or at which it has swine slaughtered that has the slaughtering capacity, alone or in combination with other plants, specified in the definition of packer in § 206.1.

(b) *What existing or available contracts do I need to provide and when are they due?* Each packer must send, to the Grain Inspection, Packers and Stockyards Administration (GIPSA), an example of each contract it currently has with a producer or producers or that is currently available at each plant that it operates or at which it has swine slaughtered that meets the definition of packer in § 206.1. This initial submission of example contracts is due to GIPSA on the first business day of the month following the determination that the plant has the slaughtering capacity, alone or in combination with other plants, specified in the definition of packer in § 206.1.

(c) *What available contracts do I need to provide and when are they due?* After the initial submission, each packer must send GIPSA an example of each new contract it makes available to a producer or producers within 1 business day of the contract being made available at each plant that it operates or at which it has swine slaughtered that meets the definition of packer in § 206.1.

(d) *What criteria do I use to select example contracts?* For purposes of distinguishing among contracts to determine which contracts may be represented by a single example, contracts will be considered to be the same if they are identical with respect to all of the following four example-contract criteria:

(1) Base price or determination of base price;

(2) Application of a ledger or accrual account (including the terms and conditions of the ledger or accrual account provision);

(3) Carcass merit premium and discount schedules (including the determination of the lean percent or other merits of the carcass that are used to determine the amount of the premiums and discounts and how those premiums and discounts are applied); and

(4) Use and amount of noncarcass merit premiums and discounts.

(e) *Where and how do I send my contracts?* Each packer may submit the example contracts, notifications required by this section, and Form P&SP 342, Contract Submission Cover Sheet, by either of the following two methods:

(1) *Electronic report.* Example contracts and notifications required by this section may be submitted by electronic means. Electronic submission may be by any form of electronic transmission that has been determined to be acceptable to the Administrator. To obtain current options for acceptable methods to submit example contracts electronically, contact GIPSA through the Internet on the GIPSA Web site (*http://www.gipsa.usda.gov*) or at USDA GIPSA, Suite 317, 210 Walnut Street, Des Moines, Iowa 50309.

(2) *Printed report.* Each packer that chooses to submit printed example contracts and notifications must deliver the printed contracts and notifications to USDA GIPSA, Suite 317, 210 Walnut Street, Des Moines, Iowa 50309.

(f) *What information from the swine contract library will be made available to the public?* GIPSA will summarize the information it has received on contract terms, including, but not limited to, base price determination and the schedules of premiums or discounts. GIPSA will make the information available by region and contract type, as defined in § 206.1, for public release 1

month after the initial submission of contracts. Geographic regions will be defined in such a manner to provide as much information as possible while maintaining confidentiality in accordance with section 251 of the Agricultural Marketing Act (7 U.S.C. 1636).

(g) *How can I review information from the swine contract library?* The information will be available on the Internet on the GIPSA Web site (*http://www.gipsa.usda.gov*) and at USDA GIPSA, Suite 317, 210 Walnut Street, Des Moines, Iowa 50309. The information will be updated as GIPSA receives information from packers.

(h) *What do I need to do when a previously submitted example contract is no longer a valid example due to contract changes, expiration, or withdrawal?* Each packer must submit a new example contract when contract changes result in changes to any of the four example-contract criteria specified in paragraph (d) of this section and notify GIPSA if the new example contract replaces the previously submitted example contract. Each packer must notify GIPSA when an example contract no longer represents any existing or available contract (expired or withdrawn). Each packer must submit these example contracts and notifications within 1 business day of the change, expiration, or withdrawal.

§ 206.3 Monthly report.

(a) *Do I need to provide monthly reports?* Each packer, as defined in § 206.1, must provide information for each swine processing plant that it operates or at which it has swine slaughtered that has the slaughtering capacity, alone or in combination with other plants, specified in the definition of packer.

(b) *When is the monthly report due?* Each packer must send a separate monthly report for each plant that has the slaughtering capacity, alone or in combination with other plants specified in the definition of packer in § 206.1. Each packer must deliver the report to the GIPSA Regional Office in Des Moines, Iowa, by the close of business on the 15th of each month, beginning at least 45 days after the initial submission of example contracts. If the 15th day of a month falls on a Saturday, Sunday, or federal holiday, the monthly report is due no later than the close of the next business day following the 15th.

(c) *What information do I need to provide in the monthly report?* The monthly report that each packer files must be reported on Form P&SP–341, which will be available on the Internet on the GIPSA Web site (*http://www.gipsa.usda.gov*) and at USDA GIPSA, Suite 317, 210 Walnut Street, Des Moines, Iowa 50309. In the monthly report, each packer must provide the following information:

(1) *Number of swine to be delivered under existing contracts.* Existing contracts are contracts the packer currently is using for the purchase of swine for slaughter at each plant. Each packer must provide monthly estimates of the number of swine committed to be delivered under all of its existing contracts (even if those contracts are not currently available for renewal or to additional producers) in each contract type as defined in § 206.1.

(2) *Available contracts.* Available contracts are the contracts the packer is currently making available to producers, or is making available for renewal to currently contracted producers, for the purchase of swine for slaughter at each plant. On the monthly report, a packer will indicate each contract type, as defined in § 206.1, that the packer is currently making available.

(3) *Estimates of committed swine.* Each packer must provide an estimate of the total number of swine committed under existing contracts for delivery to each plant for slaughter within each of the following 12 calendar months beginning with the 1st of the month immediately following the due date of the report. The estimate of total swine committed will be reported by contract type as defined in § 206.1.

(4) *Expansion clauses.* Any conditions or circumstances specified by clauses in any existing contracts that could result in an increase in the estimates specified in paragraph (c)(3) of this section. Each packer will identify the expansion clauses in the monthly report by listing a code for the following conditions:

(i) Clauses that allow for a range of the number of swine to be delivered.

(ii) Clauses that require a greater number of swine to be delivered as the contract continues.

(iii) Other clauses that provide for expansion in the numbers of swine to be delivered.

(5) *Maximum estimates of swine.* The packer's estimate of the maximum total number of swine that potentially could be delivered to each plant within each of the following 12 calendar months, if any or all of the types of expansion clauses identified in accordance with the requirement in paragraph (c)(4) of this section are executed. The estimate of maximum potential deliveries must be reported for all existing contracts by contract type as defined in § 206.1.

(d) *What if a contract does not specify the number of swine committed?* To meet the requirements of paragraphs (c)(3) and (c)(5) of this section, the packer must estimate expected and potential deliveries based on the best information available to the packer. Such information might include, for example, the producer's current and projected swine inventories and planned production.

(e) *When do I change previously reported estimates?* Regardless of any estimates for a given future month that may have been previously reported, current estimates of deliveries reported as required by paragraphs (c)(3) and (c)(5) of this section must be based on the most accurate information available at the time each report is prepared.

(f) *Where and how do I send my monthly report?* Each packer must submit monthly reports required by this section by either of the following two methods:

(1) *Electronic report.* Information reported under this section may be reported by electronic means, to the maximum extent practicable. Electronic submission may be by any form of electronic transmission that has been determined to be acceptable to the Administrator. To obtain current options for acceptable methods to submit information electronically, contact GIPSA through the Internet on the GIPSA Web site (*http://www.gipsa.usda.gov*) or at USDA GIPSA, Suite 317, 210 Walnut Street, Des Moines, Iowa 50309.

(2) *Printed report.* Each packer may deliver its printed monthly report to USDA GIPSA, Suite 317, 210 Walnut Street, Des Moines, Iowa 50309.

(g) *What information from monthly reports will be made available to the public and when and how will the information be made available to the public?* (1) *Availability.* GIPSA will provide a monthly report of estimated deliveries by contract types as reported by packers in accordance with this section, for public release on the first business day of each month. The monthly reports will be available on the Internet on the GIPSA Web site (*http://www.gipsa.usda.gov*) and at USDA GIPSA, Suite 317, 210 Walnut Street, Des Moines, Iowa 50309.

(2) *Regions.* Information in the report will be aggregated and reported by geographic regions. Geographic regions will be defined in such a manner to provide as much information as possible while maintaining confidentiality in accordance with section 251 of the Agricultural Marketing Act (7 U.S.C. 1636) and may be modified from time to time.

(3) *Reported information.* The monthly report will provide the following information:

(i) The existing contract types for each geographic region.

(ii) The contract types currently being made available to additional producers or available for renewal to currently contracted producers in each geographic region.

(iii) The sum of packers' reported estimates of the total number of swine committed by contract for delivery during the next 6 and 12 months beginning with the month the report is published. The report will indicate the number of swine committed by geographic reporting region and by contract type.

(iv) The types of conditions or circumstances as reported by packers that could result in expansion in the numbers of swine to be delivered under the terms of expansion clauses in the contracts at any time during the following 12 calendar months.

(v) The sum of packers' reported estimates of the maximum total number of swine that potentially could be delivered during each of the next 6 and 12 months if all expansion clauses in current contracts are executed. The report will indicate the sum of estimated maximum potential deliveries by geographic reporting region and by contract type.

(h) *Where and how do I file a waiver request?* The waiver request must be submitted in writing and include a statement that the packer does not procure swine using marketing agreements. The packer must send the waiver request to the GIPSA Regional Office in Des Moines, Iowa. If the waiver request is approved, GIPSA will inform the packer in writing that it has been granted a waiver for 12 months following the date of receipt of the waiver request unless the status of the packer changes during that year. The packer will be notified to submit the information required in this part if it begins using marketing agreements during the waiver period or if GIPSA determines that the packer utilizes marketing agreements.

PARTS 207–299 [RESERVED]

CHAPTER III—FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

EDITORIAL NOTE: Nomenclature changes to chapter III appear at 69 FR 18803, Apr. 9 2004.

SUBCHAPTER A—AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POULTRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION

SUBCHAPTER A—AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POULTRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION

PART 300—AGENCY MISSION AND ORGANIZATION

Sec.

AUTHORITY: 21 U.S.C. 451–470, 601–695, 1031–1056; 7 U.S.C. 138–138i, 450, 1621–1627, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 63 FR 72354, Dec. 31, 1998, unless otherwise noted.

§ 300.1 Purpose.

This part describes the duties and organization of the Food Safety and Inspection Service (FSIS), an agency of the United States Department of Agriculture (USDA). It also includes rules on the access of government employees to regulated places of business.

[63 FR 72354, Dec. 31, 1998, as amended at 69 FR 253, Jan. 5, 2004]

§ 300.2 FSIS responsibilities.

(a) *Delegations of authority.* The Secretary of Agriculture and Under Secretary for Food Safety have delegated to the Administrator of the Food Safety and Inspection Service the responsibility for exercising the functions of the Secretary of Agriculture under various statutes (see 7 CFR 2.7, 2.18, and 2.53).

(b) *Implementing regulations.* This chapter of title 9 of the Code of Federal Regulations (9 CFR chapter III) includes, in addition to administrative rules, rules and regulations that implement provisions of the following statutes:

(1) The Federal Meat Inspection Act, as amended (FMIA) (21 U.S.C. 601 *et seq.*), except provisions pertaining to the inspection and certification of the condition of animals for export, and related legislation;

(2) The Poultry Products Inspection Act, as amended (PPIA) (21 U.S.C. 451 *et seq.*);

(3) The Egg Products Inspection Act, as amended (EPIA) (21 U.S.C. 1031 *et seq.*), except for the shell egg surveillance program, voluntary laboratory analyses of egg products, and the voluntary grading program;

(4) The Humane Slaughter Act (7 U.S.C. 1901–1906);

(5) The Talmadge-Aiken Act (7 U.S.C. 450), with respect to cooperation with States in the administration of the Federal Meat Inspection Act and the Poultry Products Inspection Act;

(6) The Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627), relating to voluntary inspection of poultry and edible products thereof; voluntary inspection and certification of technical animal fat; certified products for dogs, cats, and other carnivora; voluntary inspection of rabbits and edible products thereof; and voluntary inspection and certification of edible meat and other products; and

(7) The National Laboratory Accreditation Program (7 U.S.C. 138–138i) with respect to laboratories accredited only for pesticide residue analysis in meat and poultry products.

[63 FR 72354, Dec. 31, 1998, as amended at 69 FR 253, Jan. 5, 2004]

§ 300.3 FSIS organization.

(a) *General.* The organization of FSIS reflects the Agency's primary regulatory responsibilities: implementation of the FMIA, including fish of the order Siluriformes, the PPIA, and the EPIA. FSIS implements the inspection provisions of the FMIA, the PPIA, and the EPIA through its field structure.

(b) *Headquarters.* FSIS has eight principal components or offices, each of which is under the direction of a Deputy Administrator. The Deputy Administrators, along with their staffs, and the Administrator, along with the Office of the Administrator and three

staff offices that report to the Administrator, are located at U.S. Department of Agriculture headquarters in Washington, DC.

(1) *Program Offices.* FSIS's headquarters offices are the Office of Public Health and Science, which provides scientific analysis, advice, data, and recommendations on matters involving public health and science; the Office of Management, which provides centralized administrative and support services; the Office of Policy and Program Development, which develops and articulates the Agency's policies regarding food safety and other consumer protections; the Office of Field Operations, which manages regulatory oversight and inspection (see paragraph (c) of this section); the Office of Food Security and Emergency Preparedness, which works to prevent or, if necessary, coordinate a response to an intentional attack on the food supply; the Office of Program Evaluation, Enforcement, and Review, which acts to ensure that Agency programs are functioning in an efficient and effective manner; the Office of Public Affairs, Education, and Outreach, which is responsible for facilitating communications between FSIS and Congress, the Agency's constituents, and the media; and the Office of International Affairs, which is responsible for recommending and developing international policy activities.

(2) [Reserved]

(c) *Field.* FSIS's field structure consists of eighteen district offices and a technical center.

(1) *District offices.* Each district office, under the direction of a District Manager, manages a farm-to-table food safety program of regulatory oversight and inspection in a district consisting of a State or several States and territories.

The locations of the district offices and the districts' geographic boundaries are as follows:

Alameda, CA	California.
Boulder, CO	Arizona, Colorado, Nevada, New Mexico, Utah, Alaska, American Samoa, Guam, Hawaii, Idaho, Northern Mariana Islands, Oregon, and Washington.
Salem, OR (satellite office)	
Minneapolis, MN	Minnesota, Montana, North Dakota, South Dakota, and Wyoming.
Des Moines, IA	Iowa and Nebraska.
Lawrence, KS	Kansas and Missouri.
Springdale, AR	Arkansas, Louisiana, and Oklahoma.
Dallas, TX	Texas.
Madison, WI	Michigan and Wisconsin.
Chicago, IL	Illinois, Ohio, and Indiana.
Pickering, OH, (satellite office)	
Philadelphia, PA	Pennsylvania and New Jersey.
Albany, NY	Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont.
Beltsville, MD	Delaware, District of Columbia, Maryland, Virginia, and West Virginia.
Raleigh, NC	North Carolina, South Carolina, and Kentucky.
Atlanta, GA	Florida, Georgia, Puerto Rico, and the Virgin Islands.
Jackson, MS	Alabama, Mississippi, and Tennessee.

(2) *Technical Service Center.* The Technical Service Center, which is located in Omaha, Nebraska, provides technical guidance, review, and training on the interpretation and application of regulatory requirements.

[63 FR 72354, Dec. 31, 1998, as amended at 69 FR 253, Jan. 5, 2004; 80 FR 75616, Dec. 2, 2015]

§ 300.4 Organizational terminology; personnel.

(a) Unless otherwise specifically provided or required in the context of a particular part of the regulations:

Administrator means the Administrator of the Food Safety and Inspection Service or any other officer or employee of the Department to whom authority has been or may in the future be delegated to act in his or her stead.

Circuit Supervisor means the official of the Inspection Service who is assigned responsibility for supervising the conduct of inspection at a specific group of official establishments.

Inspection program, *inspection service*, or *program* means the organizational unit within the Department with responsibility for carrying out the FMIA, the PPIA, and the EPIA.

Inspection program employee, inspection service employee, or *program employee* means an inspector or other government employee who is authorized to conduct any inspection or perform any other duty in connection with the inspection program, inspection service, or program.

Inspection service supervisor or *Inspection program supervisor* means an inspection program or service employee or program employee who is delegated authority to exercise supervision over one or more phases of the inspection program.

Inspector means an inspector of the inspection program, inspection service, and program. (''Inspector'' includes an employee or official of the Federal government or the government of a State or territory or the District of Columbia who is authorized by the Administrator to inspect meat and meat products or poultry and poultry products under the authority of the FMIA or the PPIA, respectively, under an agreement entered into between the Administrator and the appropriate State or other agency.)

Inspector in charge or *IIC* means an inspection program employee, inspection service employee, or program employee who has primary responsibility for inspection program functions at a particular official establishment.

Secretary means the Secretary of Agriculture of the United States or his or her delegate.

(b) FSIS has replaced the regional office and import field office structure referenced in some parts of subchapter A of this chapter. Authority previously delegated to Regional Directors now is delegated to district managers; authority previously delegated to area supervisors and import supervisors now is delegated to inspection program supervisors in the successor district offices.

[69 FR 253, Jan. 5, 2004]

§ 300.6 Access to establishments and other places of business.

(a) *General.* Upon presentation of credentials—

(1) Persons subject to provisions of the FMIA or the PPIA must afford representatives of the Secretary access to establishments that slaughter or otherwise prepare livestock products or process poultry products and to other places of business subject to regulation thereunder; and

(2) Persons subject to provisions of the EPIA must afford representatives of the Secretary access as specified in part 590 of this chapter.

(b) *Meat and poultry establishments and related industries.* (1) At all times, by day or night, whether the establishment is being operated or not, inspection program employees must have access to the premises and to every part of an establishment that slaughters livestock or otherwise prepares meat products or slaughters poultry or otherwise processes poultry products that are subject to inspection for the purpose of conducting an inspection or performing any other inspection program duty. The numbered official badge of an inspection program employee is sufficient identification to entitle him or her to admittance to all parts of such an establishment and its premises.

(2) At all ordinary business hours, upon presentation of credentials by a representative of the Secretary, any person (including any firm or corporation or other business unit) subject to recordkeeping requirements under section 202 of the FMIA or section 11(b) of the PPIA must permit such representative to enter his or her place of business to examine the facilities and inventory and to examine and copy the records specified in § 320.1 and § 381.175, respectively, of this chapter and, upon payment of the fair market value therefor, take reasonable samples of the inventory.

[63 FR 72354, Dec. 31, 1998, as amended at 69 FR 254, Jan. 5, 2004]

PART 301—TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

Sec.

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

§ 301.1 General.

For purposes of this chapter and unless otherwise specifically provided by

regulation or required in the context of particular regulations:

(a) Terms have the meanings set forth in this part;

(b) The singular form also imports the plural, and the masculine form also imports the feminine and vice versa.

[69 FR 254, Jan. 5, 2004]

§ 301.2 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

The Act. The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 21 U.S.C., sec. 601 *et seq.*).

Adulterated. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(iv) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: *Provided*, That an article which is not deemed adulterated under paragraphs (aa)(2) (ii), (iii), or (iv) of this section shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or,

(9) If it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise adulterated.

Anesthesia. Loss of sensation or feeling.

Animal food. Any article intended for use as food for dogs, cats, or other animals derived wholly, or in part, from the carcass or parts or products of the carcass of any livestock, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Livestock or poultry feeds manufactured from processed livestock byproducts (such as meatmeal tankage, meat and bonemeal, bloodmeal, and feed grade animal fat).

Animal food manufacturer. Any person engaged in the business of manufacturing or processing animal food.

Artificial coloring. A coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

Artificial flavoring. A flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

Biological residue. Any substance, including metabolites, remaining in livestock at time of slaughter or in any of its tissues after slaughter as the result of treatment or exposure of the livestock to a pesticide, organic or inorganic compound, hormone, hormone-like substance, growth promoter, antibiotic, anthelmintic, tranquilizer, or other therapeutic or prophylactic agent.

Capable of use as human food. This term applies to any carcass, or part or product of a carcass, of any livestock, unless it is denatured or otherwise identified as required by the applicable provisions of §§ 314.3, 314.10, 325.11, and 325.13 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., hoofs or horns in their natural state.

Captive bolt. A stunning instrument which when activated drives a bolt out of a barrel for a limited distance.

Carbon dioxide. A gaseous form of the chemical formula CO_2.

Carbon dioxide concentration. Ratio of carbon dioxide gas and atmospheric air.

Carcass. All parts, including viscera, of any slaughtered livestock.

Chemical preservative. Any chemical that, when added to a meat or meat food product, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices or substances added to meat and meat food products by exposure to wood smoke.

Other definitions, if any, that are applicable only for purposes of a specific part of the regulations in this subchapter, are set forth in such part.

Commerce. Commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

Consciousness. Responsiveness of the brain to the impressions made by the senses.

Cutting up. Any division of any carcass or part thereof, except that the trimming of carcasses or parts thereof to remove surface contaminants is not considered as cutting up.

Dead livestock. The body (cadaver) of livestock which has died otherwise than by slaughter.

Dying, diseased, or disabled livestock. Livestock which has or displays symptoms of having any of the following:

(1) Central nervous system disorder;

(2) Abnormal temperature (high or low);

(3) Difficult breathing;

(4) Abnormal swellings;

(5) Lack of muscular coordination;

(6) Inability to walk normally or stand;

(7) Any of the conditions for which livestock is required to be condemned on ante-mortem inspection in accordance with the regulations in part 309 of this subchapter.

Edible. Intended for use as human food.

Experimental animal. Any animal used in any research investigation involving the feeding or other administration of, or subjection to, an experimental biological product, drug, or chemical or any nonexperimental biological product, drug, or chemical used in a manner for which it was not intended.

Exposure time. The period of time an animal is exposed to an anesthesia-producing carbon dioxide concentration.

Federal Food, Drug, and Cosmetic Act. The Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Firm. Any partnership, association, or other unincorporated business organization.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

Immediate container. The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Inedible. Adulterated, uninspected, or not intended for use as human food.

Inhumane slaughter or handling in connection with slaughter. Slaughter or handling in connection with slaughter not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901 through 1906, as amended by the Humane Methods of Slaughter Act of 1978, 92 Stat. 1069) and part 313 of this subchapter.

''Inspected and passed'' or ''U.S. Inspected and Passed'' or ''U.S. Inspected and Passed by Department of Agriculture'' (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Labeling. All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

Livestock. Cattle, sheep, swine, goat, horse, mule, or other equine.

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

(2) [Reserved]

Meat broker. Any person engaged in the business of buying or selling carcasses, parts of carcasses, meat or meat food products of livestock on commission, or otherwise negotiating purchases or sales of such articles other than for his/her own account or as an employee of another person.

Meat byproduct. Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Meat food product. Any article capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, except those exempted from definition as a meat food product by the Administrator in specific cases or by the regulations in part 317 of this subchapter, upon a determination that they contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to assure that the meat or other portions of such carcasses contained in such articles are not adulterated and that such articles are not represented as meat food products. This term, as applied to food products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Misbranded. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (vv)(7)(ii) of this section unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of meat food and meat products, excluding labeling and packaging materials as covered in part 317 of the subchapter.

Official certificate. Any certificate prescribed by the regulations in this subchapter for issuance by an inspector or other person performing official functions under the Act.

Official device. Any device prescribed by the regulations in part 312 of this subchapter for use in applying any official mark.

Official establishment. Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at

which inspection is maintained under the regulations in this subchapter.

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in paragraph (zz) of this section, where inspections are authorized to be conducted as prescribed in § 327.6 of this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article or animal under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for meat products.

Person. Any individual, firm, or corporation.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for purposes of the Act and the regulations in this subchapter as under the Federal Food, Drug, and Cosmetic Act.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Process authority. A person or organization with expert knowledge in meat production process control and relevant regulations. This definition does not apply to part 431 of this chapter.

Process schedule. A written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. This definition does not apply to part 431 of this chapter.

Product. Any carcass, meat, meat byproduct, or meat food product, capable of use as human food.

Renderer. Any person engaged in the business of rendering carcasses or parts or products of the carcasses of any livestock except rendering conducted under inspection or exemption under Title I of the Act.

Shipping container. The outside container (box, bag, barrel, crate, or other receptacle or covering) containing or wholly or partly enclosing any product packed in one or more immediate containers.

State. Any State of the United States or the Commonwealth of Puerto Rico.

Supervision. The controls, as prescribed in instructions to Program employees, to be exercised by them over particular operations to insure that such operations are conducted in compliance with the Act and the regulations in this subchapter.

Surgical anesthesia. A state of unconsciousness measured in conformity with accepted surgical practices.

Territory. Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

U.S. Condemned. This term means that the livestock so identified has been inspected and found to be in a dying condition, or to be affected with any other condition or disease that would require condemnation of its carcass.

U.S. Inspected and Condemned (or any authorized abbreviation thereof). This term means that the carcass, viscera, other part of carcass, or other product so identified has been inspected, found to be adulterated, and condemned under the regulations in this subchapter.

U.S. Passed for Cooking. This term means that the meat or meat byproduct so identified has been inspected and passed on condition that it be cooked or rendered as prescribed by the regulations in part 315 of this chapter.

U.S. Passed for Refrigeration. This term means that the meat or meat byproduct so identified has been inspected and passed on condition that it be refrigerated or otherwise handled as prescribed by the regulations in part 311 of this subchapter.

U.S. Retained. This term means that the carcass, viscera, other part of carcass, or other product, or article so identified is held for further examination by an inspector to determine its disposal.

U.S. Suspect. This term means that the livestock so identified is suspected of being affected with a disease or condition which may require its condemnation, in whole or in part, when slaughtered, and is subject to further examination by an inspector to determine its disposal.

United States. The States, the District of Columbia, and the Territories of the United States.

[35 FR 15554, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 301.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

PART 302—APPLICATION OF INSPECTION AND OTHER REQUIREMENTS

Sec.
302.1 Establishments requiring inspection.
302.2 Application of requirements in designated States or Territories; and to designated plants endangering public health.
302.3 Livestock and products entering official establishments.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 302.1 Establishments requiring inspection.

(a) Inspection under the regulations in this subchapter is required at:

(1) Every establishment, except as provided in § 303.1 (a) and (b), or (c) of this subchapter, in which any livestock are slaughtered for transportation or sale as articles of commerce, or in which any products of, or derived from, carcasses of livestock are, wholly or in part, prepared for transportation or sale as articles of commerce, which are intended for use as human food;

(2) Every establishment, except as provided in § 303.1 (a) and (b), or (d) of this subchapter, within any State or organized Territory which is designated pursuant to paragraph 301(c) of the Act, at which any livestock are slaughtered or any products of any livestock are prepared, for use as human food solely for distribution within such jurisdiction; and

(3) Every establishment, except as provided in § 303.1 (a) and (b) of this subchapter, that is designated by the Administrator pursuant to paragraph 301(c) of the Act as one producing adulterated products which would clearly endanger the public health.

[35 FR 15556, Oct. 3, 1970, as amended at 36 FR 12002, June 24, 1971]

§ 302.2 Application of requirements in designated States or Territories; and to designated plants endangering public health.

Special provisions with respect to establishments and their operations and transactions by any persons in designated States and Territories and with respect to establishments designated as producing adulterated products which clearly endanger public health, and the operators thereof, in any State or Territory appear in part 331 of this subchapter, and apply to such establishments, operations and transactions in lieu of the regulations elsewhere in this subchapter except insofar as such regulations are made applicable by the provisions in part 331 of this subchapter.

[35 FR 15556, Oct. 3, 1970, as amended at 51 FR 29909, Aug. 21, 1986]

§ 302.3 Livestock and products entering official establishments.

All livestock and all products entering any official establishment and all products prepared, in whole or in part, therein, shall be inspected, handled, stored, prepared, packaged, marked, and labeled as required by the regulations in this subchapter.

[35 FR 15556, Oct. 3, 1970]

PART 303—EXEMPTIONS

Sec.
303.1 Exemptions.
303.2 Experimentation: Intensity of inspection coverage.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 303.1 Exemptions.

(a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:

(1) The slaughtering by any individual of livestock of his own raising,

and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock exclusively for use by him and members of his household and his nonpaying guests and employees;

(2) The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of his own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided*, That the following requirements are met by such custom operator;

(i) Establishments that conduct custom operations must be maintained and operated in accordance with the provisions of §§ 416.1 through 416.6, except for: § 416.2(g)(2) through (6) of this chapter, regarding water reuse and any provisions of part 416 of this chapter relating to inspection or supervision of specified activities or other action by a Program employee. If custom operations are conducted in an official establishment, however, all of the provisions of part 416 of this chapter of shall apply to those operations.

(ii) If the custom operator prepares or handles any products for sale, they are kept separate and apart from the custom prepared products at all times while the latter are in his custody;

(iii) The custom prepared products are plainly marked ''Not for Sale'' as provided in § 316.16 of this subchapter, immediately after being prepared and are kept so identified until delivered to the owner; and

(iv) If exempted custom slaughtering or other preparation of products is conducted in an official establishment, all facilities and equipment in the official establishment used for such custom operations shall be thoroughly cleaned and sanitized before they are used for preparing any products for sale.

(b)(1) The exempted custom prepared products shall be prepared and handled in accordance with the provisions of §§ 318.5, 318.6, 381.300 through 318.311 of this subchapter and § 424.21 of subchapter E, and shall not be adulterated as defined in paragraph 1(m) of the Act. The provisions of §§ 318.5, 318.6, and 318.300 through 318.311 related to inspection or supervision of specified activities or other action by an inspection program employee and the provisions of § 318.6(b)(9) and (10) shall not apply to the preparation and handling of such exempted products.

(2) The exempted custom prepared products shall comply with the requirements of §§ 316.16 and 317.16 of this subchapter.

(3) The custom operators claiming exemption under paragraph (a)(2) of this section shall keep records, in addition to records otherwise required by part 320 of this subchapter, showing the numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products.

(4) Articles capable of use as human food, resulting from the exempted custom slaughter or other preparation of products shall be promptly denatured or otherwise identified in accordance with § 325.13 of this subchapter and not removed from the establishment where the custom operations are conducted until so identified, unless they are delivered to the owner of the articles for use in accordance with paragraph (a)(2) of this section.

(c) It has been determined that it is impracticable to provide inspection of the preparation of products at establishments in any unorganized Territory at which livestock are slaughtered or their products are prepared for distribution solely within such jurisdiction and that exempting such establishments from requirements of the

Act for such inspections under the conditions stated in this section will otherwise facilitate enforcement of the Act. Therefore, such inspection requirements of the Act and of the regulations in this subchapter shall not apply at such establishments if they are operated in accordance with the regulations in part 416, §§ 416.1 through 416.5 of this chapter. However, the Administrator may refuse, withdraw, or modify any exemption under this paragraph when he determines in any specific case in accordance with the applicable rules of practice that such action is necessary to effectuate the purposes of this Act.

(d)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants are the following:

(*a*) Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts;

(*b*) Grinding and freezing products made from meat;

(*c*) Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;

(*d*) Breaking bulk shipments of products;

(*e*) Wrapping or rewrapping products.

(ii) Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to be a normal retail quantity if the quantity so purchased does not in the aggregate exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified:

	One-half carcass pounds
Cattle	300
Calves	37.5
Sheep	27.5
Swine	100
Goats	25

(iii) A retail store is any place of business where:

(*a*) The sales of product are made to consumers only;

(*b*) At least 75 percent, in terms of dollar value, of total sales of product represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds $500. Notice of the adjusted dollar limitation will be published in the FEDERAL REGISTER.[1]

(*c*) Only federally or State inspected and passed product is handled or used in the preparation of any product, except that product resulting from the custom slaughter or custom preparation of product may be handled or used in accordance with paragraph (a)(2) and (b) of this section but not for sale;

(*d*) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section;

(*e*) The preparation of products for sale to household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section; and

(*f*) The preparation of products for sale to other than household consumers is limited to traditional and

[1] The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food and Safety Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447–3219.

usual operations as defined in paragraph (d)(2)(i) (*a*), (*b*), (*d*), and (*e*) of this section. (A retail store at which custom slaughtering or preparation of products is conducted is not thereby disqualified from exemption as a retail store under this paragraph (d).)

(iv) *Restaurants.* (*a*) A restaurant is any establishment where:

(*1*) Product is prepared only for sale or service in meals or as entrees directly to individual consumers at such establishments;

(*2*) Only federally or State inspected and passed product or such product prepared at a retail store exempted under paragraph (d)(2)(iii) of this section is handled or used in the preparation of any product;

(*3*) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(*4*) The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(*b*) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

(*c*) For purposes of this paragraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirements of this paragraph: *Provided,* That the requirements of §§ 320.1 through 320.4 of this subchapter apply to such facility. *Provided further,* That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary, if the Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator's determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) Similar retail-type establishment: Any establishment which is a combination retail store and restaurant; any delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraphs (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) Consumer: Any household consumer, hotel, restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail store claiming exemption under this paragraph (d), in any designated State or organized Territory that is identified under section 205 of the Act (as one that does not have or is not exercising adequate authority with respect to recordkeeping requirements) has been operated in violation of the conditions prescribed in this section for exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail store and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator still has reason to believe that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail store would effectuate the purposes of the Act, the Administrator shall order the operator to maintain

complete, accurate, and legible records of total monthly purchases and of total monthly sales of meat, meat byproducts, and meat food products, in terms of dollar values of the products involved. Such records shall separately show total sales to household consumers and total sales to other consumers and shall be maintained for the period prescribed in § 320.3 of this subchapter. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to meat pizzas containing meat food product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the meat pizzas are to be served in public or private nonprofit institutions, provided that the meat pizzas are ready-to-eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1–102, except 1–102(z) and the provisions of Chapters 2 through 8, except sections 2–102(a) and (b), 2–302(d), 2–403(a), 2–403(c), 2–404, 2–405, 2–407, 2–502 through 2–506, 2–508, 2–509, 4–105, 4–201(c), 4–208, 5–101(a), 5–103, 5–104, 5–202(c), 5–203, and 6–105, part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78–2081, which is incorporated by reference, shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(3) Facilities and operations of businesses claiming this exemption shall also conform to the following requirements:

(i) *Manual cleaning and sanitizing.* (A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

(*1*) Sinks shall be cleaned prior to use.

(*2*) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(*3*) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(*4*) Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(i)(E) (*1*) through (*4*) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

(*1*) Immersion for at least ½ minute in clean, hot water at a temperature of at least 170 °F; or

(*2*) Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or

(*3*) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or

(*4*) Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or

(*5*) Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(*6*) Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(i)(E)(*4*) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

(*1*) An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and

(*2*) A numerically scaled indicating thermometer, accurate to ±3 °F, convenient to the sink for frequent checks of water temperature; and

(*3*) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) *Mechanical cleaning and sanitizing.* (A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair.

Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A ¼–inch IPS valve shall be provided immediately up stream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to ±3 °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of

wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or the use of easily movable dishtables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewashcycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: *Provided, That,*

(*1*) The temperature of the wash water shall not be less than 120 °F.

(*2*) The wash water shall be kept clean.

(*3*) Chemicals added for sanitization purposes shall be automatically dispensed.

(*4*) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(*5*) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(*6*) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(*7*) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(*1*) Single-tank, stationary-rack, dual-temperature machine:

Wash temperature	150 °F
Final rinse temperature	180 °F

(*2*) Single-tank, stationary-rack, single-temperature machine:

Wash temperature	165 °F
Final rinse temperature	165 °F

(*3*) Single-tank, conveyor machine:

Wash temperature	160 °F
Final rinse temperature	180 °F

(*4*) Multitank, conveyor machine:

Wash temperature	150 °F
Pumped rinse temperature	160 °F
Final rinse temperature	180 °F

(*5*) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):

Wash temperature	140 °F
Final rinse temperature	180 °F

(I) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) *Steam.* Steam used in contact with food or food-contact surfaces shall be free from any materials or additives other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term ''private nonprofit institution'' means ''a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of

which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.''

(5) The Administrator may withdraw or modify the exemption set forth in §303.1(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect ending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(f) The adulteration and misbranding provisions of the Act and the regulations in this subchapter, other than the requirement of the official inspection legend, apply to articles which are exempted from inspection or not required to be inspected under this section.

(g) The Administrator may extend the requirements of titles I and IV of the Act to any establishment in any State or organized Territory at which products are prepared for distribution solely within such jurisdiction, if he determines in accordance with the provisions of paragraph 301(c)(1) of the Act that it is producing adulterated products which would clearly endanger the public health.

(h) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in this subchapter in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements: *Provided*, That such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Act.

(Approved by the Office of Management and Budget under control number 0583–0015)

[35 FR 15558, Oct. 3, 1970, as amended at 36 FR 12002, 12004, June 24, 1971; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 18, 1981; 47 FR 746, Jan. 7, 1982; 51 FR 29909, Aug. 21, 1986; 52 FR 10032, Mar. 30, 1987; 52 FR 48091, Dec. 18, 1987; 53 FR 24679, June 30, 1988; 57 FR 34182, Aug. 3, 1992; 64 FR 56415, Oct. 20, 1999; 76 FR 82078, Dec. 30, 2011; 83 FR 25307, May 31, 2018]

§ 303.2 Experimentation: Intensity of inspection coverage.

(a) Pursuant to the Processed Products Inspection Improvement Act of 1986, Title IV of the Futures Trading Act of 1986 (Pub. L. 99–641), in establishments preparing products at which inspection under the Act and regulations is required, the frequency with which and the manner in which meat food products made from livestock previously slaughtered in official establishments are examined and inspected by Program employees is to be based

on considerations relevant to effective regulation of meat food products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, is so, to what extent the intensity of inspection coverage exceeds that which should be considered necessary pursuant to section 6 of the Act, as amended by section 403(a) of the Futures Trading Act of 1986, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Program employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(b) The determinations referred to in paragraph (a) of this section shall be made by the program and shall reflect evaluations of the performance and the characteristics and such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person conducting operations at such establishment or by anyone responsibly connected with the business conducting operations at such establishment, as ''responsibly connected'' is defined in section 401(g) of the Act,

(ii) The competence of the person conducting operations at such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Program employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Poultry Products Inspection Act also are prepared at such establishment, and

(vi) The size of such establishment.

(c)(1) For the period of experimentation described in paragraph (a) of this section, the frequency of inspection by Program employees of operations other than slaughter may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (b)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (b)(2) of this section,[1]

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Program employees.

(ii) To the extent that such frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this subchapter, the Administrator will waive such provisions for the period of experimentation, in accordance with §303.1(g) of this subchapter.

[52 FR 10032, Mar. 30, 1987 and 52 FR 48091, Dec. 18, 1987]

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§304.1 Application for inspection.

(a) Before the inspection is granted, each person conducting operations at an establishment subject to the Act, whether tenant, subsidiary, or landlord, shall make application therefor to the Administrator as provided for in this part.

(b) Every application under this section shall be made on an official form furnished by the Program, available from any Regional Director identified in §301.2(kkk) of this subchapter, and shall be completed to include all information requested. Trade names of the applicant for labeling purposes, shall be inserted in the appropriate blank in the application. Each applicant for inspection will be held responsible for compliance with the Act and the regulations in this subchapter if inspection is granted. Preparation of product and other operations at the establishment for which inspection is granted may be conducted only by the applicant named in the application.

(c) In cases of change of ownership or location, a new application shall be made.

[40 FR 2575, Jan. 14, 1975, as amended at 53 FR 49848, Dec. 12, 1988]

§304.2 Information to be furnished; grant or refusal of inspection.

(a) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

(b) The Administrator is authorized to grant inspection upon his determination that the applicant and the establishment are eligible therefor and to refuse to grant inspection at any establishment if he determines that it does not meet the requirements of this part or the regulations in parts 305, 307, and part 416, §§416.1 through 416.6 of this chapter or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in parts 316 and 317. Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

(c)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure

[1] These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

or refusal of the State, interstate agency or the Secretary of the Interior to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request).

(2) However, certification is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification and meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

[35 FR 15558, Oct. 3, 1970, as amended at 41 FR 4889, Feb. 3, 1976; 44 FR 68813, Nov. 30, 1979; 62 FR 45024, Aug. 25, 1997; 64 FR 56415, Oct. 20, 1999; 64 FR 66545, Nov. 29, 1999; 65 FR 2284, Jan. 14, 2000]

§ 304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an official establishment or an official import inspection establishment must have developed written Sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, as required by §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4 of this chapter.

[61 FR 38864, July 25, 1996, as amended at 77 FR 26936, May 8, 2012; 79 FR 56232, Sept. 19, 2014]

PART 305—OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

§ 305.1 Official numbers; subsidiaries and tenants.

(a) An official number shall be assigned to each establishment granted inspection. Such number shall be used to identify all inspected and passed products prepared in the establishment. More than one number shall not be assigned to an establishment.

(b) Two or more official establishments under the same ownership or control may be granted the same official number, provided a serial letter is added in each case to identify each establishment and the products thereof.

(c) When inspection has been granted to any applicant at an establishment, it shall not be granted to any other person at the same establishment. However, persons operating as separate entities in the same building or structure may operate separate establishments therein only under their own grant of inspection. All such persons operating separate establishments in the same building or structure shall be responsible for compliance with the Act and regulations in their own establishments, which shall include common

areas, e.g., hallways, stairways, and elevators.

[35 FR 15559, Oct. 3, 1970, as amended at 40 FR 2576, Jan. 14, 1975]

§ 305.2 Separation of official establishments.

(a) Each official establishment shall be separate and distinct from any unofficial establishment except a poultry products processing establishment operated under Federal inspection under the Poultry Products Inspection Act or under State inspection.

(b) The slaughter or other preparation of products of horses, mules, or other equines required to be conducted under inspection pursuant to the regulations in this subchapter shall be done in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products are prepared.

(c) Inspection shall not be inaugurated in any building, any part of which is used as living quarters, unless the part for which inspection is requested is separated from such quarters by floors, walls, and ceilings of solid concrete, brick, wood, or similar material, and the floors, walls, and ceilings are without openings that directly or indirectly communicate with any part of the building used as living quarters.

§ 305.3 Sanitation and adequate facilities.

Inspection shall not be inaugurated if an establishment is not in a sanitary condition nor unless the establishment agrees to maintain a sanitary condition and provides adequate facilities for conducting such inspection.

§ 305.4 Inauguration of inspection.

When inspection is granted, the circuit supervisor shall, at or prior to the inauguration of inspection, inform the operator of the establishment of the requirements of the regulations in this subchapter. If the establishment, at the time inspection is inaugurated, contains any product which has not theretofore been inspected, passed, and marked in compliance with the regulations in this subchapter, the identity of the same shall be maintained, and it shall not be distributed in commerce, or otherwise subject to the requirements of such regulations, or dealt with as inspected and passed under the regulations. The establishment shall adopt and enforce all necessary measures and shall comply with all such directions as the circuit supervisor may prescribe, for carrying out the purposes of this section.

§ 305.6 Reports of violations.

Program employees shall report, in a manner prescribed by the Administrator, all violations of the Act or regulations in this subchapter of which they have information.

PART 306—ASSIGNMENT AND AUTHORITIES OF PROGRAM EMPLOYEES

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

§ 306.1 Designation of circuit supervisor and assistants.

[See §§ 300.3 and 300.4 of this chapter regarding FSIS' organization and inspection program supervisors.]

[69 FR 254, Jan. 5, 2004]

§ 306.2 Program employees to have access to establishments.

[See § 300.6 of this chapter regarding access to establishments and other places of business.]

[69 FR 254, Jan. 5, 2004]

§ 306.3 Badge as identification of inspectors.

Each inspector will be furnished with a numbered official badge, which he shall not allow to leave his possession,

and which he shall wear in such manner and at such times as the Administrator may prescribe.

[35 FR 15559, Oct. 3, 1970, as amended at 69 FR 254, Jan. 5, 2004]

§ 306.4 Assignment of Program employees where members of family employed; soliciting employment; procuring product from official establishments.

(a) Except as specifically authorized by the Administrator, no Program employee shall be detailed for duty at an establishment where any member of his family is employed by the operator of the establishment, or any tenant or subsidiary of such operator nor shall any circuit supervisor or other employee acting in a supervisory capacity be continued on duty at a circuit where any member of his family is so employed at any establishment under his jurisdiction. Program employees are forbidden to solicit, for any person, employment at any official establishment, or by any officer, manager, or employee thereof.

(b) Program employees shall not procure product from any official establishment or any other establishment if its operations or products are inspected or regulated under the Poultry Products Inspection Act or the Agricultural Marketing Act of 1946, as amended, or any other law administered by the Department unless the store or outlet from which the purchase is made is open to the general public and the price paid by such employee is the same as the price paid by the general public. Program employees must pay, and obtain receipts for money paid to such establishments for all such product and keep such receipts subject to inspection by supervisory employees or other authorized Department employees.

§ 306.5 Appeals.

Any appeal from a decision of any Program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

[48 FR 11418, Mar. 18, 1983, as amended at 60 FR 67454, Dec. 29, 1995]

PART 307—FACILITIES FOR INSPECTION

Sec.

AUTHORITY: 7 U.S.C. 394, 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15560, Oct. 3, 1970, unless otherwise noted.

§ 307.1 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, shall be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the circuit supervisor and shall be conveniently located, properly ventilated and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such clothes changing facilities are deemed necessary by the circuit supervisor. At the discretion of the Administrator, small plants requiring the services of less than one full time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing shall be provided by each establishment.

§ 307.2 Other facilities and conditions to be provided by the establishment.

When required by the circuit supervisor, the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions, shall be provided by each official establishment:

(a) Satisfactory pens, equipment, and assistants for conducting ante-mortem inspection and for separating, marking and holding apart from passed livestock those marked ''U.S. suspect'' and those marked ''U.S. condemned'' (pens, alleys, and runways shall be paved, drained, and supplied with adequate hose connections for cleanup purposes);

(b) Sufficient light to be adequate for proper conduct of inspection;

(c) Racks, receptacles, or other suitable devices for retaining such parts as the head, tongue, tail, thymus gland, and viscera, and all parts and blood to be used in the preparation of meat food products or medical products, until after the post-mortem examination is completed, in order that they may be identified in case of condemnation of the carcass; equipment, trucks, and receptacles for the handling of viscera of slaughtered animals so as to prevent contact with the floor; and trucks, racks, marked receptacles, tables, and other necessary equipment for the separate and sanitary handling of carcasses or parts passed for cooking;

(d) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(e) Watertight metal trucks or receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned; such trucks or receptacles to be marked in a conspicuous manner with the phrase ''U.S. condemned'' in letters not less than 2 inches high, and, when required by the circuit supervisor, to be equipped with facilities for locking or sealing;

(f) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in dressing diseased carcasses, floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(g) In establishments in which slaughtering is done, rooms, compartments, or specially prepared open places, to be known as ''final inspection places,'' at which the final inspection of retained carcasses may be conducted (competent assistants for handling retained carcasses and parts shall be provided by the establishment; final inspection places shall be adequate in size and their rail arrangement and other equipment shall be sufficient to prevent carcasses and parts passed for food or cooking, from being contaminated by contact with condemned carcasses or parts; they shall be equipped with hot water, lavatory, sterilizer, tables, and other equipment required for ready, efficient, and sanitary conduct of the inspection; the floors shall be of such construction as to facilitate the maintenance of sanitary conditions and shall have proper drainage connections, and when the final inspection place is part of a larger floor, it shall be separated from the rest of the floor by a curb, railing, or otherwise);

(h) Retention rooms, cages, or other compartments, and receptacles in which carcasses and product may be held for further inspection (these shall be in such number and in such locations as the needs of the inspection in the establishment may require; they shall be equipped for secure locking or sealing and shall be held under locks or official seals furnished by the Department; the keys of such locks shall not leave the custody of Program employees. Every such room, compartment, or receptacle shall be marked conspicuously with the phrase ''U.S. retained'' in letters not less than 2 inches high; rooms or compartments for these purposes shall be secure and susceptible of being kept clean, including a sanitary disposal of the floor liquids; establishment employees shall not enter any retention rooms or compartments or open any retention receptacles unless authorized by Program employees);

(i) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter (tanks or other rendering equipment which, under the regulations in this subchapter, must be sealed, shall be properly equipped for sealing as specified by the regulations in part 314 of this subchapter or by the circuit supervisor in specific cases);

(j) Docks and receiving rooms, to be designated by the operator of the official establishment, with the circuit supervisor, for the receipt and inspection of all products as provided in § 318.3 of this subchapter.

(k) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) and official certificates shall be kept when not in use (all such lockers shall be equipped for sealing or locking with locks or seals to be supplied by the Department; the keys of such locks shall not leave the custody of Program employees);

(l) Sanitary facilities and accommodations as prescribed by § 416.2(c), (d), (e), (f), and (h) of this chapter.

(m) In addition to any facilities required to accomplish sanitary dressing procedures, the following inspection station facilities for cattle and swine slaughter lines described in § 310.1(b) of this subchapter are required:

(1) An inspection station consisting of 5 feet of unobstructed line space for each head or carcass inspector and, for viscera table kills, 8 feet for each viscera inspector on the inspector's side of the table.

(2) A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass.

(3) A handwash lavatory (other than one which is hand operated), furnished with soap, towels, and hot and cold water, and located adjacent to the inspector's work area. In addition, for each head and viscera inspector on cattle slaughter lines, and each head inspector on swine slaughter lines, a sterilizer located adjacent to the inspector's work area.

(4) For mechanized operations, a line control switch located adjacent to each inspection station.

(5) Facilities to position tally sheets or other recording devices, such as digital counters, and facilities to contain condemned brands.

(6) For swine slaughter lines requiring three or more inspectors, and for those one- and two-inspector configurations where the establishment installs a mirror: At the carcass inspection station one glass or plastic, distortion-free mirror, at least 5 feet × 5 feet, mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet away, and so mounted that any inspector standing at the carcass inspection station can readily view the back of the carcass.

[35 FR 15560, Oct. 3, 1970, as amended at 47 FR 33676, Aug. 4, 1982; 50 FR 19902, May 13, 1985; 64 FR 56415, Oct. 20, 1999]

§ 307.3 Inspectors to furnish and maintain implements in a sanitary condition.

Inspectors shall furnish their own work clothing and implements, such as flashlights and triers, for conducting inspection and shall maintain their implements in sanitary condition as prescribed by § 416.3(a) of this chapter.

[64 FR 56415, Oct. 20, 1999]

§ 307.4 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of a Program employee. All slaughtering of animals and preparation of products shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 consecutive hours per shift during the

basic workweek subject to the provisions of § 307.5: *Provided*, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday. The 8-hour day excludes the lunch period but shall include activities deemed necessary by the Agency to fully carry out an inspection program, including the time for FSIS inspection program personnel to put on required gear and to walk to a work station; to prepare the work station; to return from a work station and remove required gear; to sharpen knives, if necessary; and to conduct duties scheduled by FSIS, including administrative duties. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its function. These provisions are applicable to all official establishments except in certain cases as provided in § 318.4(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take into account the efficient and effective use of inspection personnel. The work schedule must specify daily clock hours of operation and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided*, however, minor deviations from a daily operating schedule may be approved by the inspector in charge, if such request is received on the day preceding the day of change.

(3) Request for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided*, That an inspector may be recalled to his assignment after completion of his daily tour of duty under the provisions of § 307.6(b).

[40 FR 45799, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986; 76 FR 33980, June 10, 2011; 77 FR 59294, Sept. 27, 2012]

§ 307.5 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday as specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall become a holiday.

[40 FR 45800, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 724, Jan. 7, 1985; 50 FR 51513, Dec. 18, 1985; 52 FR 4, Jan. 2, 1987; 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989]

§ 307.6 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 307.5(a) and at the rates specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be

considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Program employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of a Program employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45800, Oct. 3, 1975, as amended at 54 FR 6389, Feb. 10, 1989]

§ 307.7 Safety requirements for electrical stimulating (EST) equipment.

(a) *General.* Electrical stimulating (EST) equipment is equipment that provides electric shock treatment to carcasses for the purpose of accelerating rigor mortis of facilitating blood removal. These provisions do not apply to electrical equipment used to stun and/or slaughter animals or to facilitate hide removal. Electrical stimulating equipment consists of two separate pieces—the control system and the applicator. The EST control system contains the circuitry to generate pulsed DC or AC voltage for stimulation and is separate from the equipment used to apply the voltage to the carcass. The voltage is applied by inserting a probe that penetrates the carcass or is inserted in the rectum, placing a clamp in the nose, a carcass rubbar, a conveyor with energized surfaces traveling with the carcass, or any other acceptable method.

(b) *Safety requirements*—(1) *Circuits, grounding.* Either a bonded grounding conductor shall lead from each section of the carcass rail within the stimulating enclosure to the service ground, or the secondary voltage (stimulating circuit) shall be insulated from the service ground. If the stimulating section of the carcass rail and carcass drive mechanisms are insulated from the service ground then the stimulating rail or the return path shall be electrically bonded to the transformer secondary to isolate the stimulation voltage.

(2) *Enclosure.* Electrical stimulation shall occur in an area that will prevent persons from contacting an energized surface. If the area is surrounded by physical barriers, the enclosure shall be either electrically grounded or it shall be made of materials that do not conduct electricity. The interior of the stimulating area shall be visible from the start switch so the operator can be assured that there is no person, equipment or material present that should not be there prior to starting the stimulating sequence. If light or sound beam sensors form the enclosure, the stimulating equipment shall be automatically shut off when the sensor signals are broken.

(3) *Mandatory Warning Devices and Signals.* The following warning devices or signals shall be installed at each opening to the stimulating area through which a person would normally enter:

(i) A red light that flashes distinctly during the operating cycle of the stimulating equipment.

(ii) An ANSI Z53.1-Color Code sign reading (a) ''Danger Electrical Hazard'' for stimulating voltage below 50 or (b) ''Danger High Voltage'' for stimulating voltage above 50.

(iii) An emergency stop button.

(4) *Optional Warning Device—Horn or Bell.* If a warning horn or bell is installed, the signal shall be audible above background noises in the vicinity, and it shall sound for at least 1 second before each manual stimulation or before the carcass chain is started in an automatic system.

(c) *Operation*—(1) *Training.* Only persons who have received safety instruction by the equipment manufacturer or designee may operate electrical stimulating equipment.

(2) *Cleaning and Maintenance.* To prevent an electrical shock to personnel, the electricity supplied to the stimulating surfaces shall be locked-off when cleaning, mechanical inspection, maintenance or testing are performed.

(3) *Water.* To prevent an electrical shock, personnel shall not spray streams of water on energized carcasses or on energized stimulating surfaces.

(d) *Special provisions for manually operated equipment.* (1) Stimulating probes or clamps shall be stored in a sanitary container which is insulated with a material approved by the Administrator.[1]

(2) The electric wires attached to a clamp or probe shall not allow for contact between the probe or clamp and an electrical ground and shall not extend outside the enclosure.

[53 FR 46432, Nov. 17, 1988, as amended at 64 FR 56415, Oct. 20, 1999]

PART 308 [RESERVED]

PART 309—ANTE-MORTEM INSPECTION

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

[1] A list of approved insulation materials is available upon request from the Facilities, Equipment and Sanitation Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

SOURCE: 35 FR 15563, Oct. 3, 1970, unless otherwise noted.

§ 309.1 Ante-mortem inspection on premises of official establishments.

(a) All livestock offered for slaughter in an official establishment shall be examined and inspected on the day of and before slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for such examination and inspection to be made on a different day before slaughter.

(b) Such ante-mortem inspection shall be made on the premises of the establishment at which the livestock are offered for slaughter before the livestock shall be allowed to enter into any department of the establishment where they are to be slaughtered or dressed or in which edible products are handled. When the holding pens of an official establishment are located in a public stockyard and are reserved for the exclusive use of the establishment, such pens shall be regarded as part of the premises of that establishment and the operator of the establishment shall be responsible for compliance with all requirements of the regulations in this subchapter with respect to such pens.

[35 FR 15563, Oct. 3, 1970, as amended at 81 FR 46577, July 18, 2016]

§ 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

(a) Any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease or condition that, under part 311 of this subchapter would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain its identity as a suspect until it is given final post-mortem inspection, when the carcass shall be marked and disposed of as provided in parts 310 and

311 of this subchapter, or until it is disposed of as otherwise provided in this part.

(b) All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in § 311.1 of this subchapter unless they are required to be classed as condemned under § 309.3. Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(c) Livestock which have reacted to a test for leptospirosis, or anaplasmosis, but which show no symptoms of the disease, shall be identified as U.S. Suspects and disposed of as provided in § 311.10 of this subchapter.

(d) Livestock which are known to have reacted to the tuberculin test shall be identified as U.S. Suspects and disposed of as provided in § 311.2 of this subchapter, except that livestock bearing an official ''USDA Reactor'' or similar State reactor tag shall not be tagged as U.S. Suspects.

(e) Any cattle found on ante-mortem inspection to be affected with epithelioma of the eye or of the orbital region to a lesser extent than as described in § 309.6 shall be identified as a U.S. Suspect and disposed of as provided in § 311.12 of this subchapter.

(f) Cattle found on ante-mortem inspection to be affected with anasarca to a lesser extent than as described in § 309.8 shall be identified as U.S. Suspects and disposed of as provided in § 311.8 of this subchapter or paragraph (g) of this section.

(g) Any livestock suspected of being affected with anasarca may be set apart and held for treatment under Program or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period the livestock upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in § 311.8 of this subchapter or condemned and disposed of as provided in § 309.8, whichever is appropriate.

(h) All hogs suspected on ante-mortem inspection of being affected with swine erysipelas shall be identified as U.S. Suspects and disposed of as provided in § 311.5 of this subchapter or paragraph (i) of this section.

(i) A hog suspected of being affected with swine erysipelas may be set apart and held for treatment under Program or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period the animal upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in § 311.5 of this subchapter, or condemned and disposed of as provided in § 309.13, whichever is appropriate.

(j) Any livestock which is affected with vesicular exanthema or vesicular stomatitis, but which has recovered to the extent that the lesions are in process of healing, the temperature is within normal range, and the livestock shows a return to normal appetite and activity, shall be identified as U.S. Suspect and disposed of as provided in § 311.32 of this subchapter, except that if desired, such livestock may be set apart and held under supervision of a Program employee or other official designated by the area supervisor for treatment. If the livestock is set aside for treatment, the U.S. Suspect identification device will be removed by a Program employee, following such treatment, if the livestock is found to be free from any such disease. Such livestock found to be free from any such disease may be released for slaughter or for purposes other than slaughter, provided that in the latter instance, the operator of the official establishment or the owner of the animal shall first obtain permission from the local, State, or Federal livestock sanitary official having jurisdiction over the movement of such livestock.

(k) Livestock which are offered for ante-mortem inspection under this part, and which are regarded by the inspector as immature, shall be identified as U.S. Suspects and, if slaughtered, the disposition of their carcasses shall be determined by the post-mortem findings in connection with the ante-mortem conditions. If not

slaughtered as suspects, such livestock shall be held under supervision of a Program employee or other official designated by the area supervisor, and after sufficient development may be released for slaughter or may be released for any other purpose, provided they have not been exposed to any infectious or contagious disease. If such exposure occurs, permission should be obtained from the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service prior to release of such livestock.

(l) Livestock previously condemned for listeriosis, if released for slaughter under §309.13(b) shall be identified as a U.S. Suspect in accordance with §309.13(c).

(m) Each animal required by this part to be treated as a U.S. Suspect shall be identified as such by or under the supervision of a Program employee with an official device in accordance with §309.18. No such device shall be removed except by a Program employee.

(n) Each animal identified as a U.S. Suspect on ante-mortem inspection shall be set apart and shall be slaughtered separately from other livestock at that establishment unless disposed of as otherwise provided in this part.

(o) Each animal identified as a U.S. Suspect on ante-mortem inspection, when presented for slaughter shall be accompanied with a form MP 402–2 on which the inspector at the establishment shall record the U.S. Suspect identification number and any other identifying tag numbers present and a brief description of the animal and of the disease or condition for which the animal was classed as a suspect, including its temperature when the temperature of such animal might have a bearing on the disposition of the carcass on post-mortem inspection.

(p) When any animal identified as a U.S. Suspect is released for any purpose or reason, as provided in this part, the official identification device shall be removed only by a Program employee and he shall report his action to the area supervisor. When a suspect is to be released under the provisions of this part for a purpose other than slaughter, the operator of the official establishment or the owner of the animal shall first obtain permission for the removal of such animal from the local, State or Federal livestock sanitary official having jurisdiction.

[35 FR 15563, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973; 39 FR 36000, Oct. 17, 1974; 69 FR 1873, Jan. 12, 2004]

§ 309.3 Dead, dying, disabled, or diseased and similar livestock.

(a) Livestock found to be dead or in a dying condition on the premises of an official establishment shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

(b) Livestock plainly showing on ante-mortem inspection any disease or condition that, under part 311 of this subchapter, would cause condemnation of their carcasses on post-mortem inspection shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

(c) Any swine having a temperature of 106 °F. or higher and any cattle, sheep, goats, horses, mules, or other equines having a temperature of 105 °F. or higher shall be identified as U.S. Condemned. In case of doubt as to the cause of the high temperature, or when for other reasons a Program employee deems such action warranted, any such livestock may be held for a reasonable time under the supervision of a Program employee for further observation and taking of temperature before final disposition of such livestock is determined. Any livestock so held shall be reinspected on the day it is slaughtered. If, upon such reinspection, or when not held for further observation and taking of temperature, then on the original inspection, the animal has a temperature of 106 °F. or higher in the case of swine, or 105 °F. or higher in the case of other livestock, it shall be condemned and disposed of in accordance with §309.13.

(d) Any livestock found in a comatose or semicomatose condition or affected with any condition not otherwise covered in this part, which would preclude release of the animal for slaughter for human food, shall be identified ''U.S. Condemned'' and disposed of in accordance with §309.13, except that such animal may be set apart and held for further observation or

treatment under supervision of a Program employee or other official designated by the area supervisor and for final disposition in accordance with this part.

(e) Establishment personnel must notify FSIS inspection personnel when cattle become non-ambulatory disabled after passing ante-mortem inspection. Non-ambulatory disabled cattle that are offered for slaughter must be condemned and promptly disposed of in accordance with § 309.13.

[35 FR 15563, Oct. 3, 1970, as amended at 69 FR 1873, Jan. 12, 2004; 72 FR 38729, July 13, 2007; 74 FR 11466, Mar. 18, 2009; 81 FR 46577, July 18, 2016]

§ 309.4 Livestock showing symptoms of certain metabolic, toxic, nervous, or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases.

(a) All livestock showing, on ante-mortem inspection, symptoms of anaplasmosis, ketosis, leptospirosis, listeriosis, parturient paresis, pseudorabies, rabies, scrapie, tetanus, grass tetany, transport tetany, strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), dourine, acute influenza, generalized osteoporosis, glanders (farcy), acute inflammatory lameness or extensive fistula shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

(b) If any equine is suspected on ante-mortem inspection of being infected with glanders or dourine, the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service shall be so informed by a Program employee. Tests shall be performed by said unit to determine whether the animal is, in fact, infected with such disease. If it is found on such tests to be infected, the animal shall be disposed of in accordance with paragraph (a) of this section. Otherwise, the animal shall be identified as a U.S. Suspect and disposed of as provided in § 311.10 of this subchapter.

[35 FR 15563, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973]

§ 309.5 Swine; disposal because of hog cholera.

(a) All swine found by an inspector to be affected with hog cholera shall be identified as U.S. Condemned and disposed of in accordance with § 309.13. Immediate notification shall be given by the inspector to the official in the Veterinary Services unit of the Animal and Plant Health Inspection Service who has responsibility for the control of swine diseases in the State where the swine are located.

(b) All swine, even though not themselves identified as U.S. Suspects, which are of lots in which one or more animals have been condemned or identified as U.S. Suspect for hog cholera, shall, as far as possible, be slaughtered separately and apart from all other livestock passed on ante-mortem inspection.

[40 FR 27225, June 27, 1975]

§ 309.6 Epithelioma of the eye.

Any animal found on ante-mortem inspection to be affected with epithelioma of the eye and the orbital region in which the eye has been destroyed or obscured by neoplastic tissue and which shows extensive infection, suppuration, and necrosis, usually accompanied with foul odor, or any animal affected with epithelioma of the eye or of the orbital region which, regardless of extent, is accompanied with cachexia shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

§ 309.7 Livestock affected with anthrax; cleaning and disinfection of infected livestock pens and driveways.

(a) Any livestock found on ante-mortem inspection to be affected with anthrax shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

(b) No other livestock of a lot in which anthrax is found on ante-mortem inspection shall be slaughtered and presented for post-mortem inspection until it has been determined by a careful ante-mortem inspection that no anthrax infected livestock remains in the lot.

(c) Apparently healthy livestock (other than hogs) from a lot in which

anthrax is detected, and any apparently healthy livestock which have been treated with anthrax biologicals which do not contain living anthrax organisms, may be slaughtered and presented for post-mortem inspection if they have been held not less than 21 days following the last treatment or the last death of any livestock in the lot. Alternatively, if desired, all apparently healthy livestock of the lot may be segregated and held for treatment by a State licensed veterinarian under supervision of a Program employee or other official designated by the area supervisor. No anthrax vaccine (live organisms) shall be used on the premises of an official establishment.

(d) Livestock which have been injected with anthrax vaccines (live organisms) within 6 weeks, and those bearing evidence of reaction to such treatment, such as inflammation, tumefaction, or edema at the site of the injection, shall be condemned on antemortem inspection, or such animals may be held under supervision of a Program employee or other official designated by the area supervisor until the expiration of the 6-week period and the disappearance of any evidence of reaction to the treatment.

(e) When livestock are found on antemortem inspection to be affected with anthrax, all exposed livestock pens and driveways of the official establishment shall be cleaned and disinfected by promptly and thoroughly removing and burning all straw, litter, and manure. This shall be followed immediately by a thorough disinfection of the exposed premises by soaking the ground, fences, gates, and all exposed material with a 5 percent solution of sodium hydroxide or commercial lye prepared as outlined in §310.9(e)(1) of this subchapter, or other disinfectant that may be approved in specific cases by the Administrator specifically for this purpose.

§ 309.8 Cattle affected with anasarca and generalized edema.

All cattle found on ante-mortem inspection to be affected with anasarca in advanced stages and characterized by an extensive and generalized edema shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

§ 309.9 Swine erysipelas.

All hogs plainly showing on antemortem inspection that they are affected with acute swine erysipelas shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

§ 309.10 Onset of parturition.

Any livestock showing signs of the onset of parturition shall be withheld from slaughter until after parturition and passage of the placenta. Slaughter or other disposition may then be permitted if the animal is otherwise acceptable.

§ 309.11 Vaccine livestock.

Vaccine livestock with unhealed lesions of vaccinia, accompanied with fever, which have not been exposed to any other infectious or contagious disease, are not required to be slaughtered and may be released for removal from the premises.

§ 309.12 Emergency slaughter; inspection prior to.

In all cases of emergency slaughter, except as provided in §311.27 of this subchapter, the animals shall be inspected immediately before slaughter, whether theretofore inspected or not. When the necessity for emergency slaughter exists, the establishment shall notify the inspector in charge so that such inspection may be made.

§ 309.13 Disposition of condemned livestock.

(a) Except as otherwise provided in this part, livestock identified as U.S. Condemned shall be killed by the official establishment, if not already dead. Such animals shall not be taken into the official establishment to be slaughtered or dressed; nor shall they be conveyed into any department of the establishment used for edible products; but they shall be disposed of in the manner provided for condemned carcasses in part 314 of this subchapter. The official U.S. Condemned tag shall not be removed from, but shall remain on the carcass until it goes into the tank, or is otherwise disposed of as prescribed in part 314 of this subchapter,

at which time such tag may be removed by a Program employee only. The number of such tag shall be reported to the veterinary medical officer by the inspector who affixed it, and also by the inspector who supervised the tanking of the carcass.

(b) Any livestock condemned on account of ketosis, swine erysipelas, vesicular diseases, grass tetany, transport tetany, parturient paresis, anasarca, anaplasmosis, leptospirosis, listeriosis, or inflammatory condition including pneumonia, enteritis, and peritonitis may be set apart and held for treatment under supervision of a Program employee or official designated by the area supervisor. The U.S. Condemned identification tag will be removed by a Program employee following treatment under such supervision if the animal is found to be free from any such disease.

(c) Livestock previously affected with listeriosis, including those released for slaughter after treatment under paragraph (b) of this section, shall be identified as U.S. Suspect.

(d) When livestock under the provisions of this section is to be released for a purpose other than slaughter, the operator of the official establishment or the owner of the livestock shall first obtain permission for the movement of such livestock from the local, State, or Federal livestock sanitary official having jurisdiction.

[35 FR 15563, Oct. 3, 1970, as amended at 72 FR 38729, July 13, 2007; 81 FR 46577, July 18, 2016]

§ 309.14 Brucellosis-reactor goats.

Goats which have reacted to a test for brucellosis shall not be slaughtered in an official establishment.

§ 309.15 Vesicular diseases.

(a) Immediate notification shall be given by the inspector to the local, State, and Federal livestock sanitary officials having jurisdiction when any livestock is found to be affected with a vesicular disease.

(b) No livestock under quarantine by State or Federal livestock sanitary officials on account of a vesicular disease will be given ante-mortem inspection. If no quarantine is invoked, or if quarantine is invoked and later removed, upon ante-mortem inspection, any animal found to be affected with vesicular exanthema or vesicular stomatitis in the acute stages, as evidenced by acute and active lesions or an elevated temperature, shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

§ 309.16 Livestock suspected of having biological residues.

(a) Except as provided by paragraph (d) of this section, livestock suspected of having been treated with or exposed to any substance that may impart a biological residue which would make the edible tissues unfit for human food or otherwise adulterated shall be handled in compliance with the provisions of this paragraph. They shall be identified at official establishments as ''U.S. Condemned.'' These livestock may be held under the custody of a Program employee, or other official designated by the Administrator, until metabolic processes have reduced the residue sufficiently to make the tissues fit for human food and otherwise not adulterated. When the required time has elapsed, the livestock, if returned for slaughter, must be re-examined on ante-mortem inspection. To aid in determining the amount of residue present in the tissues, officials of the Program may permit the slaughter of any such livestock for the purpose of collecting tissues for analysis for the residue. Such analysis may include the use of inplant screening procedures designed to detect the presence of antimicrobial residues in any species of livestock.

(b) All carcasses and edible organs and other parts thereof, in which are found any biological residues which render such articles adulterated, shall be marked as ''U.S. Condemned'' and disposed of in accordance with § 314.1 or § 314.3 of this chapter.

(c) [Reserved]

(d) Calves shall not be presented for ante-mortem inspection in an official establishment except under the provisions of this paragraph.

(1) *Definitions.* For purposes of this paragraph, the following definitions shall apply:

(i) *Calf.* A calf up to 3 weeks of age or up to 150 pounds.

(ii) *Certified calf.* A calf that the producer and all other subsequent custodians of the calf certify in writing has not been treated with any animal drug while in his or her custody or has been treated with one or more drugs in accordance with FDA approved label directions while in his or her custody and has been withheld from slaughter for the period(s) of time specified by those label directions.

(iii) *Healthy calf.* A calf that an inspector determines shows no visual signs of disease or treatment of disease at ante-mortem inspection.

(iv) *Producer.* The owner of the calf at the time of its birth.

(v) *Sick calf.* A calf that an inspector on ante-mortem inspection determines has either signs of treatment or signs of disease.

(vi) *Veterinary medical officer.* An inspector of the Program that has obtained a Doctor of Veterinary Medicine degree which is recognized by the Program.

(2) *General requirements.* (i) The identity of the producer of each calf presented for ante-mortem inspection shall be made available by the official establishment to the inspection prior to the animal being presented for ante-mortem inspection.

(ii) The inspector shall segregate the calves presented for ante-mortem inspection at the establishment and identify each calf as one of the following: (a) Certified, (B) noncertified, or (C) previous residue condemnation.

(3) *Certified group.* (i) For a calf to be considered certified, the producer and all other subsequent custodians of the calf must certify in writing that while the calf was in his or her custody, the calf was not treated with animal drugs or was treated with one or more drugs in accordance with FDA approved label directions and was withheld from slaughter for the period(s) of time specified by those label directions. All prior certifications must be presented with the animal at the time of slaughter. The certifications shall contain a list of the calves with accompanying identification numbers, as required by paragraph (d)(3)(ii) of this section, followed by the following language:

I hereby certify that, while in my custody, from _____ to _____ (time period of custody), the above-listed calf or calves have not been treated with drugs, or have been treated with one or more drugs in accordance with FDA approved label directions and have been withheld from slaughter for the period(s) of time specified by those label directions. I certify that, to the best of my knowledge and belief, all information contained herein is true, that the information may be relied upon at the official establishment, and that I understand that any willful falsification of this certification is a felony and may result in a fine of up to $250,000 for an individual or up to $500,000 for an organization, or imprisonment for not more than 5 years, or both (21 U.S.C. 677, 18 U.S.C. 1001 and 3571).

Executed on _____
(date of certification)

_____
(signature of certifier)

_____
(typed or printed name and address of certifier)

_____
(business of certifier)

(ii) Each calf must be identified by use of backtag, eartag, or other type of secure identification which displays a number which shall be recorded on all written certifications.

(iii) The inspector shall have segregated for veterinary medical officer examination any certified calf which he or she determines to show any sign of disease or which is not identified individually. Such animal will be tagged as ''U.S. Suspect'' and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21 (c) and (d).

(iv) The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(c) and (d).

(4) *Noncertified group.* On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or she determines to show any sign of disease. Such animal will be tagged as ''U.S. Suspect'' and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21(c). The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(c).

(5) *Calves from producers with previous residue condemnation.* On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or

she determines to show any sign of disease. Such animal will be tagged as ''U.S. Suspect'' and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21(e). The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(e).

(e) The name of each and all person(s) who sold or consigned each swine to the establishment shall be made available by the establishment to any Program employee or other authorized employee of the United States Department of Agriculture upon that employee's request and presentation of his or her official credentials. Swine identification, by means approved by the Animal and Plant Health Inspection Service, USDA, under part 71 of this title, must be maintained throughout post-mortem inspection, in accordance with § 310.23(a) of this subchapter.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0053)

[36 FR 24928, Dec. 24, 1971, as amended at 44 FR 45606, Aug. 3, 1979; 44 FR 59499, Oct. 16, 1979; 47 FR 746, Jan. 7, 1982; 47 FR 41336, Sept. 20, 1982; 50 FR 32164, Aug. 9, 1985; 50 FR 53127, Dec. 30, 1985; 52 FR 2104, Jan. 20, 1987; 53 FR 40387, Oct. 14, 1988; 55 FR 7474, Mar. 2, 1990]

§ 309.17 Livestock used for research.

(a) No livestock used in any research investigation involving an experimental biological product, drug, or chemical shall be eligible for slaughter at an official establishment unless:

(1) The operator of such establishment, the sponsor of the investigation, or the investigator has submitted to the Program, or the Veterinary Services unit of the Animal and Plant Health Inspection Service of the Department of Agriculture or to the Environmental Protection Agency or to the Food and Drug Administration of the Department of Health, Education, and Welfare, data or a summary evaluation of the data which demonstrates that the use of such biological product, drug, or chemical will not result in the products of such livestock being adulterated, and a Program employee has approved such slaughter;

(2) Written approval by the Deputy Administrator, Meat and Poultry Inspection Field Operations is furnished the area supervisor prior to the time of slaughter;

(3) In the case of an animal administered any unlicensed, experimental veterinary biologic product regulated under the Virus-Serum Toxin Act (21 U.S.C. 151 *et seq.*), the product was prepared and distributed in compliance with Part 103 of the regulations issued under said Act (part 103 of this title), and used in accordance with the labeling approved under said regulations;

(4) In the case of an animal administered any investigational drug regulated under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*), the drug was prepared and distributed in compliance with the applicable provisions of part 135 of the regulations issued under said Act (21 CFR part 135), and used in accordance with the labeling approved under said regulations;

(5) In the case of an animal subjected to any experimental economic poison under section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 135 *et seq.*), the product was prepared and distributed in accordance with § 362.17 of the regulations issued under said Act (7 CFR 362.17), and used in accordance with the labeling approved under said regulations.

(6) In the case of an animal administered or subjected to any substance that is a food additive or pesticide chemical under the Federal Food, Drug, and Cosmetic Act, supra, there has been compliance with all tolerance limitations established by said Act and the regulations promulgated thereunder (21 CFR 1.1 *et seq.*), and all other restrictions and requirements imposed by said Act and said regulations will be complied with at the time of slaughter.

(b) The inspector in charge may deny or withdraw the approval for slaughter of any livestock subject to the provision of this section when he deems it necessary to assure that all products prepared at the official establishment are free from adulteration.

§ 309.18 Official marks and devices for purposes of ante-mortem inspection.

(a) All livestock required by this part to be identified as U.S. Suspects shall

be tagged with a serially numbered metal ear tag bearing the term ''U.S. Suspect,'' except as provided in §309.2(d) and except that cattle affected with epithelioma of the eye, antinomycosis, or actinobacillosis to such an extent that the lesions would be readily detected on post-mortem inspection, need not be individually tagged on ante-mortem inspection with the U.S. Suspect tag, provided that such cattle are segregated and otherwise handled as U.S. Suspects.

(b) In addition, identification of U.S. Suspect swine must include the use of tattoos specified by the inspector to maintain the identity of the animals through the dehairing equipment when such equipment is used.

(c) All livestock required by this part to be identified as U.S. Condemned shall be tagged with a serially numbered metal ear tag bearing the term ''U.S. Condemned.''

(d) The devices described in paragraphs (a), (b), and (c) of this section shall be the official devices for identification of livestock required to be identified as U.S. Suspect or U.S. Condemned as provided in this part.

PART 310—POST-MORTEM INSPECTION

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15567, Oct. 3, 1970, unless otherwise noted.

§310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.

(a) A careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments. Such inspection and examination shall be made at the time of slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for making such inspection and examination at a later time.

(b)(1) The staffing standards on the basis of the number of carcasses to be inspected per hour are outlined in the following tables. Standards for multiple inspector lines are based on inspectors rotating through the different types of inspection stations during each shift to equalize the workload. The inspector in charge shall have the authority to require the establishment to reduce slaughter line speeds where,

in his judgment, the inspection procedure cannot be adequately performed at the current line speed because of particular deficiencies in carcass preparation and presentation by the plant at the higher speed, or because the health condition of the particular animals indicates a need for more extensive inspection.

(2) *Cattle inspection.* For all cattle staffing standards, an ''a'' in the ''Number of Inspectors by Stations'' column means that one inspector performs the entire inspection procedure and a ''b'' means that one inspector performs the head and lower carcass inspection and a second inspector performs the viscera and upper carcass inspection. [1]

(i) Inspection Using the Viscera Truck.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 27	a	a	a
28 to 56	b	b	b
57 to 84	1	1	1
85 to 86	1	2	1
87 to 143	2	2	1

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 27	a	a	a
28 to 55	b	b	b
56 to 77	1	1	1
78 to 81	1	2	1
82 to 134	2	2	1

(A) Rules for determining adjusted maximum slaughter rates for single-inspector kills considering walking distance according to the table in this subdivision: Determine the distances the inspector actually walks between the points shown in columns 2 through 14 of the following table. For each column, determine the deduction figure opposite the appropriate number of feet in column 1. Compute the total of the deduction figures for columns 2 through 14. The adjusted maximum rate is the maximum rate in paragraph (b)(2)(i) of this section minus total of the deduction figures. If the resultant number is not a whole number, it must be rounded off to the next *lowest* whole number.

[1] The ''Maximum Slaughter Rates'' figures listed in paragraph (b)(2)(i) of this section for one (a) and two (b) inspector kills are overstated because the time required to walk from one inspection station to another is not included. To determine the proper adjusted maximum slaughter line speed, paragraph (b)(2)(i)(A) of this section for one inspector kills or paragraph (b)(2)(i)(B) of this section for two inspector kills must be used along with their accompanying rules.

ONE-INSPECTOR CATTLE KILL—VISCERA TRUCK

[Table of deductions from maximum slaughter rates for each 2 feet between points (in tenths of cattle per hour)]

1 Number of feet between points	2 Head rack and high rail		3 Viscera and low rail		4 Low rail and head rack		5 Head rack and carcass[2]		6 Carcass[2] and washbasin		7 Tags—brands and low rail		8 Viscera and washbasin		9 Viscera and high rail		10 Low rail and high rail		11 Head rack and closest washbasin		12 Washbasin and high rail[1]		13 Head rack and washbasin[1]		14 Viscera and tags—brands	
	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.1	0
5	0	0	0.1	0	0	0	0	0	0	0	0	0	0.1	0.1	0.1	0.1	0	0	0	0	0	0	0	0	0.2	0.1
7	0	0	0.1	0.1	0.1	0.1	0	0	0	0	0.1	0.1	0.1	0.2	0.2	0.2	0.1	0.1	0	0	0	0	0	0	0.3	0.3
9	0	0	0.2	0.1	0.1	0.1	0	0	0	0	0.1	0.2	0.1	0.3	0.3	0.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.4	0.4
11	0.1	0.1	0.2	0.2	0.2	0.2	0	0	0	0	0.1	0.2	0.2	0.4	0.4	0.4	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.5	0.6
13	0.1	0.1	0.3	0.2	0.2	0.2	0	0	0	0	0.2	0.2	0.2	0.5	0.5	0.5	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.6	0.7
15	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.2	0.3	0.3	0.5	0.6	0.6	0.3	0.3	0	0	0.2	0.2	0.2	0.2	0.7	0.9
17	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.3	0.3	0.3	0.6	0.7	0.7	0.3	0.3	0	0.1	0.2	0.2	0.2	0.2	0.9	1.0
19	0.1	0.1	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.7	0.8	0.8	0.4	0.4	0	0.1	0.2	0.2	0.2	0.2	1.0	1.1
21	0.2	0.2	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.8	0.9	0.8	0.4	0.4	0	0.1	0.3	0.2	0.3	0.2	1.1	1.3
23	0.2	0.2	0.6	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.5	0.9	1.0	0.9	0.5	0.5	0	0.1	0.3	0.3	0.3	0.3	1.2	1.4
25	0.2	0.2	0.7	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.5	1.0	1.1	1.0	0.5	0.5	0	0.1	0.3	0.3	0.3	0.3	1.3	1.5
27	0.2	0.2	0.7	0.5	0.6	0.5	0	0	0	0	0.4	0.5	0.6	1.1	1.2	1.1	0.6	0.6	0	0.1	0.3	0.3	0.3	0.3	1.4	1.7
29	0.2	0.2	0.8	0.6	0.6	0.6	0	0	0	0	0.5	0.6	0.6	1.2	1.3	1.2	0.6	0.6	0	0.1	0.4	0.3	0.4	0.3	1.5	1.8
31	0.3	0.2	0.8	0.6	0.7	0.6	0	0	0	0	0.5	0.6	0.7	1.3	1.3	1.4	0.7	0.7	0	0.1	0.4	0.4	0.4	0.4	1.6	1.9
33	0.3	0.3	0.9	0.7	0.7	0.7	0	0	0	0	0.6	0.7	0.7	1.3	1.4	1.4	0.7	0.7	0	0.1	0.4	0.4	0.4	0.4	1.7	2.1
35	0.3	0.3	1.0	0.7	0.8	0.7	0	0	0	0	0.6	0.7	0.8	1.4	1.5	1.5	0.8	0.8	0	0.2	0.5	0.4	0.5	0.4	1.8	2.2
37	0.3	0.3	1.0	0.8	0.8	0.8	0	0	0	0	0.6	0.8	0.8	1.5	1.6	1.6	0.8	0.8	0	0.2	0.5	0.5	0.5	0.5	1.9	2.3
39	0.3	0.3	1.1	0.8	0.9	0.8	0	0	0	0	0.7	0.8	0.9	1.6	1.7	1.7	0.9	0.9	0	0.2	0.5	0.5	0.5	0.5	2.0	2.4
41	0.4	0.3	1.1	0.9	0.9	0.9	0	0.1	0	0.1	0.7	0.9	0.9	1.7	1.7	1.8	0.9	0.9	0	0.2	0.6	0.5	0.6	0.5	2.1	2.6
43	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.7	0.9	1.0	1.8	1.8	1.9	1.0	1.0	0.1	0.2	0.6	0.5	0.6	0.5	2.2	2.7
45	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.8	0.9	1.0	1.8	1.9	2.0	1.0	1.0	0.1	0.2	0.6	0.6	0.6	0.6	2.3	2.8
47	0.4	0.4	1.3	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	1.9	2.0	2.1	1.1	1.1	0.1	0.2	0.6	0.6	0.6	0.6	2.4	2.9
49	0.4	0.4	1.4	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	2.0	2.1	2.2	1.1	1.1	0.1	0.2	0.7	0.6	0.7	0.6	2.5	3.1
51	0.5	0.5	1.4	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.1	2.2	2.2	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.6	3.2
53	0.5	0.5	1.5	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.2	2.3	2.3	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.7	3.3
55	0.5	0.5	1.5	1.2	1.2	1.2	0	0.1	0	0.1	1.0	1.2	1.2	2.3	2.4	2.4	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.8	3.4
57	0.5	0.5	1.6	1.2	1.3	1.2	0	0.1	0	0.1	1.0	1.2	1.3	2.3	2.4	2.5	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.9	3.5
59	0.5	0.5	1.6	1.3	1.3	1.3	0	0.1	0	0.1	1.0	1.3	1.3	2.4	2.5	2.6	1.4	1.4	0.1	0.3	0.8	0.8	0.8	0.8	3.0	3.6

[1] The washbasin referred to here is the one the inspector uses while enroute from the head rack to high rail inspection.
[2] This refers to the carcass in the bleeding area.

(B) Rules for determining adjusted maximum slaughter rates for two-inspector kills considering walking distance according to the table in this subdivision: Determine the distances the inspectors actually walk between the points shown in columns 2 through 9 of the following table. Column 9 is used only if the condemned brands and tags the viscera inspector uses are kept at a location other than at the wash-basin-sterilizer. For each column, determine the deduction figure opposite the appropriate number of feet in column 1. Compute the total of the deduction figures for columns 2 through 9. Divide this total by 2. The adjusted maximum rate is the maximum rate in paragraph (b)(2)(i) of this section minus the number calculated above. If the resultant number is not a whole number, it must be rounded off to the next *lowest* whole number.

TWO-INSPECTOR CATTLE KILL—VISCERA TRUCK

[Table of deductions from maximum slaughter rates for each 2 feet between points (in tenths of cattle per hour)]

	Heads and low rail inspection								Viscera and high rail inspection							
1	2		3		4		5		6		7		8		9[1]	
Number of feet between points	Head rack and washbasin		Head rack and carcasses[2]		Washbasin and low rail		Head rack and low rail		Viscera and brands tags (washbasin)		Viscera and high rail		High rail and washbasin		Viscera and washbasin	
	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0.1	0	0.1	0	0.1	0	0	0	0	0	0	0	0	0	0.1	0.2
5	0.1	0.1	0.1	0.1	0.1	0.1	0.8	0.7	0.4	0.5	0.5	0.5	0.1	0.2	0.2	0.3
7	0.1	0.2	0.1	0.1	0.1	0.1	1.5	1.4	0.7	0.9	1.0	0.9	0.3	0.3	0.3	0.4
9	0.2	0.2	0.1	0.2	0.1	0.2	2.2	2.0	1.1	1.3	1.5	1.3	0.4	0.5	0.4	0.5
11	0.2	0.3	0.1	0.2	0.2	0.2	2.8	2.7	1.4	1.7	1.9	1.8	0.5	0.6	0.4	0.6
13	0.2	0.4	0.1	0.3	0.2	0.2	3.5	3.3	1.7	2.1	2.4	2.2	0.6	0.7	0.5	0.8
15	0.3	0.4	0.1	0.3	0.2	0.3	4.1	3.9	2.0	2.5	2.9	2.6	0.7	0.9	0.6	0.9
17	0.3	0.5	0.1	0.4	0.2	0.3	4.8	4.5	2.4	2.9	3.3	3.0	0.8	1.0	0.7	1.0
19	0.3	0.6	0.2	0.4	0.3	0.4	5.4	5.1	2.7	3.3	3.7	3.4	0.9	1.2	0.7	1.2
21	0.3	0.6	0.2	0.4	0.3	0.4	6.0	5.7	3.0	3.7	4.2	3.7	1.0	1.3	0.8	1.3
23	0.4	0.7	0.2	0.5	0.3	0.5	6.6	6.3	3.3	4.0	4.6	4.1	1.2	1.4	0.9	1.4
25	0.4	0.7	0.2	0.5	0.3	0.5	7.2	6.8	3.6	4.4	5.0	4.5	1.3	1.6	1.0	1.6
27	0.4	0.8	0.2	0.6	0.4	0.5	7.8	7.4	3.9	4.7	5.4	4.9	1.4	1.7	1.0	1.7
29	0.5	0.9	0.2	0.6	0.4	0.6	8.3	7.9	4.2	5.1	5.8	5.2	1.5	1.8	1.1	1.8
31	0.5	0.9	0.2	0.7	0.4	0.6	8.9	8.5	4.5	5.4	6.2	5.6	1.6	2.0	1.2	2.0
33	0.5	1.0	0.2	0.7	0.4	0.7	9.4	9.0	4.8	5.8	6.5	5.9	1.7	2.1	1.3	2.1
35	0.6	1.1	0.3	0.8	0.5	0.7	10.0	9.5	5.0	6.1	6.9	6.3	1.8	2.2	1.3	2.3
37	0.6	1.1	0.3	0.8	0.5	0.7	10.5	10.0	5.3	6.4	7.3	6.6	1.9	2.4	1.4	2.4
39	0.6	1.2	0.3	0.9	0.5	0.8	11.0	10.5	5.6	6.8	7.6	6.9	2.0	2.5	1.5	2.5
41	0.7	1.2	0.3	0.9	0.6	0.8	11.5	11.0	5.9	7.1	8.0	7.2	2.1	2.6	1.5	2.6
43	0.7	1.3	0.3	0.9	0.6	0.9	12.0	11.4	6.1	7.4	8.3	7.6	2.2	2.8	1.6	2.8
45	0.7	1.4	0.3	1.0	0.6	0.9	12.5	11.9	6.4	7.7	8.7	7.9	2.4	2.9	1.7	2.9
47	0.8	1.4	0.3	1.0	0.6	1.0	13.0	12.4	6.7	8.0	9.0	8.2	2.5	3.0	1.8	3.0
49	0.8	1.5	0.3	1.1	0.7	1.0	13.4	12.8	6.9	8.3	9.4	8.5	2.6	3.2	1.8	3.1
51	0.8	1.6	0.3	1.1	0.7	1.0	13.9	13.3	7.2	8.6	9.7	8.8	2.7	3.3	1.9	3.3
53	0.9	1.6	0.4	1.2	0.7	1.1	14.4	13.7	7.4	8.9	10.0	9.1	2.8	3.4	2.0	3.4
55	0.9	1.7	0.4	1.2	0.7	1.1	14.8	14.1	7.7	9.2	10.3	9.4	2.9	3.5	2.0	3.5
57	0.9	1.7	0.4	1.3	0.8	1.2	15.2	14.6	7.9	9.5	10.6	9.7	3.0	3.7	2.1	3.6
59	0.9	1.8	0.4	1.3	0.8	1.2	15.7	15.0	8.2	9.7	10.9	9.9	3.1	3.8	2.2	3.8

[1] This column to be used only if brands and tags are not located at the washbasin.
[2] This refers to the carcasses in the bleeding area.

(ii) Inspection Using Viscera Table, Tongue-In Presentation of Heads.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 32	a	a	a
33 to 58	b	b	b
59 to 84	1	1	1
85 to 86	1	2	1
87 to 143	2	2	1
144 to 171	3	2	1
172 to 198	3	3	1
199 to 226	3	3	2
227 to 253	4	3	2
254 to 280	4	4	2
281 to 306	5	4	2
307 to 333	5	5	2

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 29	a	a	a
30 to 56	b	b	b
57 to 77	1	1	1
78 to 81	1	2	1
82 to 134	2	2	1
135 to 159	2	3	1
160 to 187	3	3	1
188 to 213	3	4	1
214 to 234	3	4	2
235 to 264	4	4	2
265 to 289	5	4	2
290 to 314	5	5	2

(iii) Inspection Using Viscera Table, Tongue-Out Presentation of Heads.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 32	a	a	a
33 to 58	b	b	b
59 to 86	1	1	1
87 to 103	1	2	1
104 to 156	2	2	1
157 to 186	2	3	1
187 to 216	3	3	1
217 to 246	3	3	2
247 to 275	3	4	2
276 to 304	4	4	2
305 to 333	4	5	2
334 to 362	5	5	2
363 to 390	5	6	2

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 29	a	a	a
30 to 56	b	b	b
57 to 79	1	1	1
80 to 98	1	2	1
99 to 147	2	2	1
148 to 174	2	3	1
175 to 205	3	3	1
206 to 233	3	4	1
234 to 256	3	4	2
257 to 288	4	4	2
289 to 316	5	4	2
317 to 343	5	5	2

(3) *Swine Inspection.* The following inspection staffing standards are applicable to swine slaughter configurations. The inspection standards for all slaughter lines are based upon the observation rather than palpation, at the viscera inspection station, of the spleen, liver, heart, lungs, and mediastinal lymph nodes. In addition, for one- and two-inspector lines, the standards are based upon the distance walked (in feet) by the inspector between work stations; and for three or more inspector slaughter lines, upon the use of a mirror, as described in §307.2(m)(6), at the carcass inspection station. Although not required in a one- or two-inspector slaughter configuration, except in certain cases as determined by the inspection service, if a mirror is used, it must comply with the requirements of §307.2(m)(6).

TABLE 1—ONE INSPECTOR—STAFFING STANDARDS FOR SWINE

Distance walked[1] in feet is—	Maximum inspection rates (head per hour)			
	Market hogs (heads attached or detached)		Sows and boars (heads detached)	
	Without mirror	With mirror	Without mirror	With mirror
0 to 5	140	150	131	143
6 to 10	134	144	126	137
11 to 15	129	137	122	132
16 to 20	124	132	117	127
21 to 35	120	127	113	122
26 to 30	116	122	110	118
31 to 35	112	118	106	114
36 to 40	108	114	103	110
41 to 45	105	110	100	106
46 to 50	101	107	97	103
51 to 55	98	103	94	100
56 to 60	96	100	91	97
61 to 65	93	97	89	94
66 to 70	90	95	87	92

TABLE 1—ONE INSPECTOR—STAFFING STANDARDS FOR SWINE—Continued

Distance walked[1] in feet is—	Maximum inspection rates (head per hour)			
	Market hogs (heads attached or detached)		Sows and boars (heads detached)	
	Without mirror	With mirror	Without mirror	With mirror
71 to 75	88	92	85	89
76 to 80	86	89	82	87
81 to 85	84	87	80	85
86 to 90	82	85	79	83
91 to 95	80	83	77	81
96 to 100	78	81	75	79

[1] Distance walked is the total distance that the inspector will have to walk between work stations during one inspection cycle (e.g., between viscera, carcass, head, and wash-basin).

TABLE 2—TWO INSPECTORS—STAFFING STANDARDS FOR MARKET HOGS

Distance walked[1] in feet by inspector B is—	Maximum inspection rates (head per hour with heads attached or detached)		
	Line configuration		
	Carcass,[2] head viscera[3]	Viscera,[2] head carcass[3]	Head,[2] viscera carcass[3]
Without Mirror			
0 to 5	151–253	151–271	151–296
6 to 10	151–239	151–255	151–277
11 to 15	151–226	151–240	151–260
16 to 20	151–214	151–227	151–244
21 to 25	151–204	151–215	151–231
With Mirror			
0 to 5	151–253	151–303	151–318
6 to 10	151–239	151–283	151–304
11 to 15	151–226	151–265	151–289
16 to 20	151–214	151–249	151–270
21 to 25	151–204	151–235	151–254

[1] Distance walked is the total distance that Inspector B will have to walk between work stations during one inspection cycle (e.g., between viscera, carcass, and washbasin).
[2] Inspector A.
[3] Inspector B.

NOTE: In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

TABLE 3—TWO INSPECTORS—STAFFING STANDARDS FOR SOWS AND BOARS

Distance walked[1] in feet by inspector B is—	Maximum inspection rates (head per hour)			
	Line Configuration			
	Carcass,[2] head viscera,[3] heads detached	Viscera,[2] head carcass,[3] heads detached	Head,[2] viscera carcass,[3] heads detached	Head,[2] viscera carcass,[3] heads attached
Without Mirror				
0 to 5	144–248	144–254	144–267	144–267
6 to 10	144–235	144–240	144–253	144–253
11 to 15	144–222	144–227	144–239	144–239
16 to 20	144–211	144–215	144–226	144–226
21 to 25	144–201	144–205	144–214	144–214
With Mirror				
0 to 5	144–248	144–292	144–305	144–292
6 to 10	144–235	144–273	144–291	144–280
11 to 15	144–222	144–256	144–272	144–268
16 to 20	144–211	144–241	144–255	144–255
21 to 25	144–201	144–228	144–240	144–240

[1] Distance walked is the total distance that Inspector B will have to walk between work stations during one inspection cycle (e.g., between viscera, carcass, and washbasin).
[2] Inspector A.
[3] Inspector B.

NOTE: In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

TABLE 4—THREE INSPECTORS OR MORE—STAFFING STANDARDS FOR SWINE

Maximum inspection rates (head per hour with heads attached)	Number of inspectors by station			
	Head	Viscera	Carcass	Total
Market hogs:				
319 to 506	1	1	1	3
507 to 540	1	2	1	4
541 to 859	2	2	1	5
860 to 1,022	2	3	1	6
1,023 to 1,106	3	3	1	7
Sows and boars:				
306 to 439	1	1	1	3
306 to 462[1]	1	1	1	3
440 to 475	2	1	1	4
476 to 752	2	2	1	5
753 to 895	3	2	1	6
896 to 964	3	3	1	7

[1] This rate applies if the heads of sows and boars are *detached* from the carcasses at the time of inspection.

NOTE: In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

[35 FR 15567, Oct. 3, 1970, as amended at 47 FR 33676, Aug. 4, 1982; 50 FR 19903, May 13, 1985]

§ 310.2 Identification of carcass with certain severed parts thereof and with animal from which derived.

(a) The head, tail, tongue, thymus gland, and all viscera of each slaughtered animal, and all blood and other parts of such animal to be used in the preparation of meat food products or medical products, shall be handled in such a manner as to identify them with the rest of the carcass and as being derived from the particular animal involved, until the post-mortem examination of the carcass and parts thereof has been completed. Such handling shall include the retention of ear tags, backtags, implants, and other identifying devices affixed to the animal, in such a way to relate them to the carcass until the post-mortem examination has been completed.

(b) The official State-Federal Department backtag on any carcass shall:

(1)(i) Be removed from the hide of the animal by an establishment employee and placed in a clear plastic bag. The bag containing the tag shall be affixed to the corresponding carcass.

(ii) The bag containing the tag shall be removed from the carcass by an establishment employee and presented with the viscera to the Program inspector at the point where such inspector conducts the viscera inspection.

(2)(i) Brucellosis and tuberculosis ear tags, herd identification ear tags, sales tags, ear bangles, and similar identification devices shall be removed from the animal's hide or ear by an establishment employee and shall be placed in a clear plastic bag and affixed to the corresponding carcass.

(ii) The bag containing the tag shall be removed from the carcass by an establishment employee and presented with the viscera to the Program inspector at the point where such inspector conducts the viscera inspection.

(3) In cases where both types of devices described in paragraphs (b)(1) and (2) of this section are present on the same animal, both types may be placed in the same plastic bag or in two separate bags.

(4) The circuit supervisor may allow the use of any alternate method proposed by the operator of an official establishment for handling the type of devices described in paragraph (b)(2) of this section if such alternate method would provide a ready means of identifying a specific carcass with the corresponding devices by a Program inspector during the post-mortem inspection.

(5) Disposition and use of identifying devices.

(i) The official State-Federal Department backtags will be collected by a Program inspector and used to obtain traceback information necessary for proper disposition of the animal or carcass and otherwise handled according to instructions issued to the inspectors.

(ii) The devices described in paragraph (b)(2) of this section shall be collected by the Program inspector when required to obtain traceback information necessary for proper disposition of the animal or carcass and for controlling the slaughter of reactor animals. Devices not collected for these purposes shall be discarded after the post-mortem examination is complete.

(6) Plastic bags used by the establishment for collecting identifying devices will be furnished by the Department.

[35 FR 15567, Oct. 3, 1970; 36 FR 12004, June 24, 1971]

§ 310.3 Carcasses and parts in certain instances to be retained.

Each carcass, including all detached organs and other parts, in which any lesion or other condition is found that might render the meat or any part unfit for food purposes, or otherwise adulterated, and which for that reason would require a subsequent inspection, shall be retained by the Program employee at the time of inspection. The identity of every such retained carcass, detached organ, or other part shall be maintained until the final inspection has been completed. Retained carcasses shall not be washed or trimmed unless authorized by the Program employee.

§ 310.4 Identification of carcasses and parts; tagging.

Such devices and methods as may be approved by the Administrator may be used for the temporary identification of retained carcasses, organs, and other parts. In all cases, the identification shall be further established by affixing

''U.S. Retained'' tags as soon as practicable and before final inspection. These tags shall not be removed except by a Program employee.

§ 310.5 Condemned carcasses and parts to be so marked; tanking; separation.

Each carcass or part which is found on final inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated shall be conspicuously marked, on the surface tissues thereof, by a Program employee at the time of inspection, as ''U.S. Inspected and Condemned.'' Condemned detached organs and other parts of such character that they cannot be so marked shall be placed immediately in trucks or receptacles which shall be kept plainly marked ''U.S. Condemned,'' in letters not less than 2 inches high. All condemned carcasses and parts shall remain in the custody of a Program employee and shall be disposed of as required in the regulations in part 314 of this subchapter at or before the close of the day on which they are condemned.

§ 310.6 Carcasses and parts passed for cooking; marking.

Carcasses and parts passed for cooking shall be marked conspicuously on the surface tissues thereof by a Program employee at the time of inspection, ''U.S. Passed for Cooking.'' All such carcasses and parts shall be cooked in accordance with part 315 of this subchapter, and until so cooked shall remain in the custody of a Program employee.

§ 310.7 Removal of spermatic cords, pizzles and preputial diverticuli.

Spermatic cords and pizzles shall be removed from all carcasses. Preputial diverticuli shall be removed from hog carcasses.

§ 310.8 Passing and marking of carcasses and parts.

Carcasses and parts found to be sound, healthful, wholesome, and otherwise not adulterated shall be passed and marked as provided in part 316 of this subchapter. In all cases where carcasses showing localized lesions are passed for food or for cooking and ''U.S. Retained'' tags are attached to the carcasses, the affected tissues shall be removed and condemned before the tags are removed. ''U.S. Retained'' tags shall be removed only by a Program employee.

§ 310.9 Anthrax; carcasses not to be eviscerated; disposition of affected carcasses; hides, hoofs, horns, hair, viscera and contents, and fat; handling of blood and scalding vat water; general cleanup and disinfection.

(a) Carcasses found before evisceration to be affected with anthrax shall not be eviscerated but shall be retained, condemned, and immediately tanked or otherwise disposed of as provided in part 314 of this subchapter.

(b) All carcasses and all parts, including hides, hoofs, horns, hair, viscera and contents, blood, and fat of any livestock found to be affected with anthrax shall be condemned and immediately disposed of as provided in part 314 of this subchapter, except that the blood may be handled through the usual blood cooking and drying equipment.

(c) Any part of any carcass that is contaminated with anthrax-infected material through contact with soiled instruments or otherwise shall be immediately condemned and disposed of as provided in part 314 of this subchapter.

(d) The scalding vat water through which hog carcasses affected with anthrax have passed shall be immediately drained into the sewer and all parts of the scalding vat shall be cleaned and disinfected as provided in paragraph (e) of this section.

(e)(1) That portion of the slaughtering department, including the bleeding area, scalding vat, gambrelling bench, floors, walls, posts, platforms, saws, cleavers, knives, and hooks, as well as employees' boots and aprons, contaminated through contact with anthrax-infected material, shall, except as provided in paragraph (e)(2) of this section be cleaned immediately and disinfected with one of the following

disinfectants or other disinfectant[1] approved specifically for this purpose by the Administrator:

(i) A 5 percent solution of sodium hydroxide or commercial lye containing at least 94 percent of sodium hydroxide. The solution shall be freshly prepared immediately before use by dissolving 2½ pounds of sodium hydroxide or lye in 5½ gallons of hot water and shall be applied as near scalding hot as possible to be most effective. (Owing to the extremely caustic nature of sodium hydroxide solution, precautionary measures such as the wearing of rubber gloves and boots to protect the hands and feet, and goggles to protect the eyes, should be taken by those engaged in the disinfection process. It is also advisable to have an acid solution, such as vinegar, in readiness in case any of the sodium hydroxide solution should come in contact with any part of the body.)

(ii) A solution of sodium hypochlorite containing approximately one-half of 1 percent (5,000 parts per million) of available chlorine. The solution shall be freshly prepared.

(iii) When a disinfectant solution has been applied to equipment which will afterwards contact product, the equipment shall be rinsed with clean water before such contact.

(2) In case anthrax infection is found in the hog slaughtering department, an immediate preliminary disinfection shall be made from the head-dropper's station to the point where the disease is detected and the affected carcasses shall be cut down from the rail and removed from the room. Upon completion of the slaughtering of the lot of hogs of which the anthrax-infected animals were a part, slaughtering operations shall cease, and a thorough cleanup and disinfection shall be made, as provided in paragraph (e)(1) of this section. If the slaughter of the lot has not been completed by the close of the day on which anthrax was detected, the cleanup and disinfection shall not be deferred beyond the close of that day.

[1] A list of disinfectants approved for this purpose is available upon request to the Scientific Services, Meat and Poultry Inspection, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(3) The first and indispensable precautionary step for persons who have handled anthrax material is thorough cleansing of the hands and arms with liquid soap and running hot water. It is important that this step be taken immediately after exposure, before vegetative anthrax organisms have had time to form spores. In the cleansing, a brush or other appropriate appliance shall be used to insure the removal of all contaminating material from under and about the fingernails. This process of cleansing is most effective when performed in repeated cycles of lathering and rinsing rather than in spending the same amount of time in scrubbing with a single lathering. After the hands have been cleansed thoroughly and rinsed free of soap, they may, if desired, be immersed for about 1 minute in a 1:1,000 solution of bichloride of mercury, followed by thorough rinsing in clean running water. Supplies of bichloride of mercury for the purpose must be held in the custody of the veterinary medical officer. (As a precautionary measure, all persons exposed to anthrax infection should report promptly any suspicious condition (sore or carbuncle) or symptom to a physician, in order that anti-anthrax serum or other treatment may be administered as indicated.)

[35 FR 15567, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 310.10 Carcasses with skin or hide on; cleaning before evisceration; removal of larvae of Hypodermae, external parasites and other pathological skin conditions.

When a carcass is to be dressed with the skin or hide left on, the skin or hide shall be thoroughly washed and cleaned before any incision is made for the purpose of removing any part thereof or evisceration, except that where calves are slaughtered by the kosher method, the heads shall be removed from the carcasses, before washing of the carcasses. The skin shall be removed at the time of post-mortem inspection from any calf carcass infested with the larvae of the ''oxwarble'' fly (Hypoderma lineata and Hypoderma bovis), or external parasites, or affected with other pathological skin conditions.

§ 310.11 Cleaning of hog carcasses before incising.

All hair, scurf, dirt, hoofs and claws shall be removed from hog carcasses, and the carcasses shall be thoroughly washed and cleaned before any incision is made for inspection or evisceration.

§ 310.12 Sternum to be split; abdominal and thoracic viscera to be removed.

The sternum of each carcass shall be split and the abdominal and thoracic viscera shall be removed at the time of slaughter in order to allow proper inspection.

§ 310.13 Inflating carcasses or parts thereof; transferring caul or other fat.

(a) Establishments that slaughter livestock and prepare livestock carcasses and parts may inflate carcasses or parts of carcasses with air if they develop, implement, and maintain controls to ensure that the air inflation procedure does not cause insanitary conditions or adulterate product. Establishments shall incorporate these controls into their HACCP plans or Sanitation SOPs or other prerequisite programs.

(b)(1) Transferring the caul or other fat from a fat to a lean carcass is prohibited.

(2) Injecting compressed air into the skulls of cattle in conjunction with a captive bolt stunner to hold the animal still for dressing operations is prohibited.

(Approved by the Office of Management and Budget under control number 0583–0015)

[54 FR 36756, Sept. 5, 1989, as amended at 55 FR 29565, July 20, 1990; 69 FR 1891, Jan. 12, 2004; 75 FR 69577, Nov. 15, 2010]

§ 310.14 Handling of bruised parts.

When only a portion of a carcass is to be condemned on account of slight bruises, either the bruised portion shall be removed immediately and disposed of in accordance with part 314 of this subchapter, or the carcass shall be promptly placed in a retaining room and kept until chilled and the bruised portion shall then be removed and disposed of as provided in part 314 of this subchapter.

§ 310.15 Disposition of thyroid glands and laryngeal muscle tissue.

(a) Livestock thyroid glands and laryngeal muscle tissue shall not be used for human food.

(b) Livestock thyroid glands and laryngeal muscle tissue may be distributed to pharmaceutical manufacturers for pharmaceutical use in accordance with § 314.9 or § 325.19(c) of this subchapter, if they are labeled in accordance with § 316.13(f) of this subchapter. Otherwise, they shall be disposed of at the official establishment in accordance with § 314.1 or § 314.3 of this subchapter.

[53 FR 45890, Nov. 15, 1988]

§ 310.16 Disposition of lungs.

(a) Livestock lungs shall not be saved for use as human food.

(b) Lungs found to be affected with disease or pathology and lungs found to be adulterated with chemical or biological residue shall be condemned and identified as ''U.S. Inspected and Condemned.'' Condemned lungs may not be saved for pet food or other nonhuman food purposes. They shall be maintained under inspectional control and disposed of in accordance with §§ 314.1 and 314.3 of this subchapter.

(c) Lungs not condemned under paragraph (b) of this section may be used in the preparation of pet food or for other nonhuman food purposes at the official establishment, provided they are handled in the manner prescribed in § 318.12 of this subchapter, or they may be distributed from the establishment in commerce, or otherwise, in accordance with the conditions prescribed in § 325.8 of this subchapter for nonhuman food purposes or they may be so distributed to pharmaceutical manufacturers for pharmaceutical use in accordance with §§ 314.9 and 325.19(b) of this subchapter, if they are labeled as ''Inedible [SPECIES] Lungs—for Pharmaceutical Use Only.'' Otherwise, they shall be disposed of at the official establishment, in accordance with §§ 314.1 and 314.3 of this subchapter.

[36 FR 11639, June 17, 1971]

§ 310.17 Inspection of mammary glands.

(a) Lactating mammary glands and diseased mammary glands of cattle, sheep, swine, and goats shall be removed without opening the milk ducts or sinuses. If pus or other objectionable material is permitted to come in contact with the carcass, the parts of the carcass thus contaminated shall be removed and condemned.

(b) Nonlactating cow udders may be saved for food purposes provided suitable facilities for handling and inspecting them are provided. Examination of udders by palpation shall be done by a Program employee. When necessary, in the judgment of the Program employee for adequate inspection, the official establishment employees shall incise udders in sections no greater than 2 inches in thickness. All udders showing disease lesions shall be condemned by a Program employee. Each udder shall be properly identified with its respective carcass and kept separate and apart from other udders until its disposal has been accomplished in accordance with the provisions of part 311 of this subchapter.

(c) Lactating mammary glands of cattle, sheep, swine, and goats shall not be saved for edible purposes.

(d) The udders from cows officially designated as ''Brucellosis reactors'' or as ''Mastitis elimination cows'' shall be condemned.

§ 310.18 Contamination of carcasses, organs, or other parts.

(a) Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector.

(b) Brains, cheek meat, and head trimmings from animals stunned by lead, sponge iron, or frangible bullets shall not be saved for use as human food but shall be handled as described in § 314.1 or § 314.3 of this subchapter.

§ 310.19 Inspection of kidneys.

An employee of the establishment shall open the kidney capsule and expose the kidneys of all livestock at the time of slaughter for the purpose of examination by a Program employee.

§ 310.20 Saving of blood from livestock as an edible product.

Blood may be saved for edible purposes at official establishments provided it is derived from livestock, the carcasses of which are inspected and passed, and the blood is collected, defibrinated, and handled in a manner so as not to render it adulterated under the Federal Meat Inspection Act and regulations issued pursuant thereto. The defibrination of blood intended for human food purposes shall not be done with the hands. Anticoagulants may be used in accordance with 21 CFR chapter I, subchapter A and subchapter B, or by regulation in 9 CFR chapter III, subchapter A or subchapter E.

[64 FR 72174, Dec. 23, 1999]

§ 310.21 Carcasses suspected of containing sulfa and antibiotic residues; sampling frequency; disposition of affected carcasses and parts.

(a) Calf carcasses from animals suspected of containing biological residues under § 309.16(d) of this subchapter shall, on post-mortem inspection, be handled in accordance with the provisions of this section.

(b) For purposes of this section, the following definitions shall apply:

(1) *Calf*. A calf up to 3 weeks of age or up to 150 pounds.

(2) *Certified calf*. A calf that the producer and all other subsequent custodians of the calf certify in writing has not been treated with any animal drug while in his or her custody or has been treated with one or more drugs in accordance with FDA approved label directions while in his or her custody and has been withheld from slaughter for the period(s) of time specified by those label directions.

(3) *Healthy carcass*. A carcass that an inspector determines shows no lesions of disease or signs of disease treatment at post-mortem inspection

(4) *Producer*. The owner of the calf at the time of its birth.

(5) *Sick calf carcass*. A calf carcass that an inspector on post-mortem inspection determines has either signs of disease treatment or lesions of disease

or was from an animal identified as sick on ante-mortem.

(6) *Sign of treatment.* Sign of treatment of a disease is indicated by leakage around jugular veins, subcutaneous, intramuscular or intraperitoneal injection lesions, or discoloration from particles or oral treatment in any part of the digestive tract.

(7) *Veterinary medical officer.* An inspector of the Program that has obtained a Doctor of Veterinary Medicine degree which is recognized by the Program.

(c) *Selection of carcasses for testing.* The inspector shall perform a swab bioassay test[1] on:

(1) Any carcass from a calf tagged as ''U.S. Suspect'' at the time of ante-mortem inspection, except that calves whose carcasses are condemned for pathology shall not be tested for drug residues.

(2) Any carcass which he/she finds has either lesions of disease which is not condemned because of these lesions or a sign of treatment of disease at the time of post-mortem inspection,

(3) Any carcass of a calf from a producer whose calf or calves have previously been condemned for residues as prescribed in paragraph (e) of this section, and

(4) Carcasses from healthy-appearing certified and noncertified calves, as determined by the veterinary medical officer during ante-mortem inspection, will be selected for testing as set forth below:

Testing level	Sampling Rate (percent of estimated day's slaughter)	
	Certified	Noncertified
A	100	100
B	50	50
C	20	30
(Start) D	5	10
E	2	5
F	1	2

[1]The procedures for performing the swab bioassay test are set forth in one of two self-instructional guides: ''Performing the CAST'' or ''Fast Antimicrobial Screen Test.'' These guides are available for review in the office of the FSIS Docket Clerk, Room 4352 South, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) *Testing of carcasses:*

(1) The inspector shall test all carcasses as prescribed in paragraph (c) of this section.

(2) Upon initiation of this program at an establishment, the inspector shall begin the testing rate for carcasses from healthy-appearing certified and noncertified calves at Level D as prescribed in paragraph (c)(4) of this section. The inspector shall increase the testing rate to the next higher level the following business day when three carcasses in 100 or less consecutively tested show a positive test result for a drug residue. The inspector shall decrease it to the next lower level when no more than two calves show a positive test result for a drug residue in either 500 calves consecutively tested or all calves tested over a 60 working day period.

(3) Test results shall be determined by the veterinary medical officer.

(4) The establishment may designate one or more of its employees to aid the inspector in performing the swab bioassay test under the supervision of the veterinary medical officer who shall interpret the results, maintain animal identification with the test unit, and ensure integrity of the testing program.

(5) All carcasses and parts thereof from calves selected for testing shall be retained until all test results are complete.

(6) The veterinary medical officer shall condemn all carcasses and parts thereof for which there are positive test results and release for human consumption all carcasses and parts thereof for which there are negative test results.

(7) If there is a positive test result, subsequent calves from the producer of the calf shall be tested in accordance with paragraph (e) of this section. These test results will not be included in computations to determine an establishment's compliance record.

(8) The veterinary medical officer may reduce inspection line rates when, in his/her judgment, the prescribed testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for extensive testing.

(e) *Calves from producers with a previous residue condemnation.* The inspector shall perform a swab bioassay test on all carcasses of all calves in the group. The veterinary medical officer shall determine the test results and shall condemn any carcass and parts thereof for which there is a positive test result and pass for human consumption any such carcass and parts thereof for which there is a negative test result. All subsequent calves from the same producer which has previously sold or delivered to official establishments any carcass that was condemned because of drug residues must be tested according to this paragraph until five consecutive animals test completely free of animal drug residues.

(f) If the owner or operator of an official establishment disagrees with the veterinary medical officer's disposition of carcasses and parts thereof, the owner or operator may appeal as provided in section 306.5 of this chapter.

[50 FR 32164, Aug. 9, 1985, as amended at 52 FR 2104, Jan. 20, 1987; 55 FR 7475, Mar. 2, 1990; 60 FR 66483, Dec. 22, 1995]

§ 310.22 Specified risk materials from cattle and their handling and disposition.

(a) The following materials from cattle are specified risk materials, except when they are from cattle from a country that can demonstrate that its bovine spongiform encephalopathy (BSE) risk status can reasonable be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States:

(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older and

(2) The distal ileum of the small intestine and the tonsils from all cattle.

(b) Specified risk materials are inedible and prohibited for use as human food.

(c) Specified risk materials must be removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with § 314.1 or § 314.3 of this subchapter. The spinal cord from cattle 30 months of age and older must be removed from the carcass at the establishment where the animal was slaughtered.

(d) *Requirements for use of the small intestine for human food.* (1) The small intestine from all cattle may be used for human food if:

(i) It is derived from cattle that were inspected and passed in an official establishment in the United States or in a certified foreign establishment in a country listed in 9 CFR 327.2(b) as eligible to export meat and meat products to the United States and it is otherwise eligible for importation under 9 CFR 327.1(b), and

(ii) The distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

(iii) If the conditions in paragraphs (d)(1)(i) or (ii) of this section are not met, the entire small intestine must be removed from the carcass, segregated from edible materials, and disposed of in accordance with §§ 314.1 or 314.3 of this subchapter.

(2) The requirements in paragraph (d)(1) of this section do not apply to materials from cattle from countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting specified risk materials for use as human food does in the United States.

(e) *Procedures for the removal, segregation, and disposition of specified risk materials.* (1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. These procedures must address potential contamination of edible materials with specified risk materials before, during, and

after entry into the establishment. Establishments must incorporate their procedures for the removal, segregation, and disposition of specified risk materials into their HACCP plans or Sanitation SOPs or other prerequisite programs.

(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of these procedures, have failed to ensure that specified risk materials are adequately and effectively removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified risk materials in preventing the use of these materials for human food and must revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) *Recordkeeping requirements.* (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section must be retained for at least one year and must be accessible to FSIS. All such records must be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(f) *Sanitation of equipment used to cut through specified risk materials.* (1) If an establishment that slaughters cattle, or that processes the carcasses or parts from cattle, does not segregate the carcasses and parts from cattle 30 months of age and older from the carcasses and parts from cattle younger than 30 months during processing operations it must:

(i) Use dedicated equipment to cut through specified risk materials; or

(ii) Clean and sanitize equipment used to cut through specified risk materials before the equipment is used on carcasses or parts from cattle younger than 30 months of age.

(2) If an establishments that slaughters cattle, or that process the carcasses or parts from cattle, segregates the carcasses and parts of cattle 30 months of age and older from cattle younger than 30 months of age during processing operations, and processes the carcasses or parts from the cattle younger than 30 months first, it may use routine operational sanitation procedures on equipment used to cut through specified risk materials.

(g) Slaughter establishments may ship beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected establishment for further processing if the establishment shipping these materials:

(1) Maintains control of the carcasses or parts while they are in transit or ensures that the carcasses or parts move under FSIS control;

(2) Ensures that the carcasses or parts are accompanied by documentation that clearly states that the carcasses or parts contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter;

(3) Maintains records that identify the official establishment that received the carcasses or parts;

(4) Maintains records that verify that the official establishment that received the carcasses or parts removed the portions of the vertebral column designated as specified risk materials in

paragraph (a)(1) of this section and disposed of them in accordance with § 314.1 or § 314.3 of this subchapter.

(h) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate through documentation that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

[72 FR 38729, July 13, 2007]

§ 310.23 Identification of carcasses and parts of swine.

(a) The identification of the carcasses and parts of swine identified in accordance with part 71 of this title shall be made available to the inspector upon the inspector's request throughout post-mortem inspection.

(b) If the establishment fails to provide required swine identification, the inspector shall order the retention of swine caracasses at the establishment until the completion of tests to confirm that the carcasses are not adulterated.

[53 FR 40387, Oct. 14, 1988]≤

§ 310.24 [Reserved]

§ 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; *E. coli* testing. (1) Each official establishment that slaughters livestock must test for *Escherichia coli* Biotype 1 (*E.coli*) Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) *Written procedures*. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection*. The establishment must collect samples from all chilled livestock carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples must be collected in the following manner;

(A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank, brisket and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.

(iii) *Sampling frequency*. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the volume of production at the following rates:

(A) Cattle, sheep, goats, horses, mules, and other equines: 1 test per 300 carcasses, but, a minimum of one sample during each week of operation.

Swine: 1 test per 1,000 carcasses, but a minimum of one sample during each week of operation.

(iv) *Sampling frequency alternatives*. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that

the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) *Sampling in very low volume establishments.* (A) Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000 horses, mules or other equines, 20,000 swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of CFU/cm^2 of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) *Criteria for evaluation of test results.* (i) An establishment excising samples from carcasses is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1—EVALUATION OF E. COLI TEST RESULTS

Type of livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Cattle	Negative[a]	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000 CFU/cm^2	13	3

[a] Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 cfu/cm^2 carcass surface area.

(ii) Establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques.

[2] A copy of the current edition/revision of the ''Official Methods of AOAC International,'' 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a) (1)–(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standard; *Salmonella*—(1) *Raw meat product performance standards for Salmonella.* An establishment's raw meat products, when sampled and tested by FSIS for *Salmonella,* as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2—SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for *Salmonella*) [a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	[b] N.A.	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are available in the FSIS Docket Room.

[b] Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) *Enforcement.* FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products. [3]

(3) *Noncompliance and establishment response.* When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

[61 FR 38864, July 25, 1996, as amended at 62 FR 26217, May 13, 1997; 63 FR 1735, Jan. 12, 1998; 64 FR 66553, Nov. 29, 1999]

PART 311—DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

Sec.

[3] A copy of FSIS's ''Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15569, Oct. 3, 1970, unless otherwise noted.

§ 311.1 Disposal of diseased or otherwise adulterated carcasses and parts; general.

(a) The carcasses or parts of carcasses of all animals slaughtered at an official establishment and found at the time of slaughter or at any subsequent inspection to be affected with any of the diseases or conditions named in this part shall be disposed of according to the section pertaining to the disease or condition: *Provided*, That no product shall be passed for human food under any such section unless it is found to be otherwise not adulterated. Products passed for cooking or refrigeration under this part must be so handled at the official establishment where they are initially prepared unless they are moved to another official establishment for such handling or in the case of products passed for refrigeration are moved for such refrigeration to a freezing facility approved by the Administrator in specific cases: *Provided*, That when so moved the products are shipped in containers sealed in accordance with § 318.10(c) of this subchapter or in a sealed means of conveyance as provided in § 325.7 of this subchapter. Owning to the fact that it is impracticable to formulate rules covering every case and to designate at just what stage a disease process or a condition results in adulteration of a product, the decision as to the disposal of all carcasses, organs, or other parts not specifically covered in this part shall be left to the veterinary medical officer. The veterinary medical officer shall exercise his judgment regarding the disposition of all carcasses or parts of carcasses under this part in a manner which will insure that only wholesome, unadulterated product is passed for human food.

(b) In cases of doubt as to a condition, a disease, or the cause of a condition, or to confirm a diagnosis, representative specimens of the affected tissues, properly prepared and packaged, shall be sent for examination to one of the laboratories of the Biological Control Section of the Program.

§ 311.2 Tuberculosis.

The following principles shall apply to the disposition of carcasses of livestock based on the difference in the pathogenesis of tuberculosis in swine, cattle, sheep, goats, and equines.

(a) *Carcasses condemned.* The entire carcass of swine, cattle, sheep, goats, and equines shall be condemned if any of the following conditions occur:

(1) When the lesions of tuberculosis are generalized (tuberculosis is considered to be generalized when the lesions are distributed in a manner made possible only by entry of the bacilli into the systemic circulation);

(2) When on ante mortem inspection the animal is observed to have a fever found to be associated with an active tuberculosis lesion on post mortem inspection;

(3) When there is an associated cachexia;

(4) When a tuberculosis lesion is found in any muscle or intermuscular tissue, or bone, or joint, or abdominal organ (excluding the gastrointestinal tract) or in any lymph node as a result of draining a muscle, bone, joint, or abdominal organ (excluding the gastrointestinal tract);

(5) When the lesions are extensive in tissues of either the thoracic or the abdominal cavity;

(6) When the lesions are multiple, acute, and actively progressive; or

(7) When the character or extent of the lesions otherwise is not indicative of a localized condition.

(b) *Organs or other parts condemned.* An organ or other part of a swine, cattle, sheep, goat, or equine carcass affected by localized tuberculosis shall be condemned when it contains lesions of tuberculosis or when the corresponding lymph node contains lesions of tuberculosis.

(c) *Carcasses of cattle passed without restriction for human food.* Carcasses of cattle may be passed without restriction for human food only when the carcass of an animal not identified as a reactor to a tuberculin test administered by an Animal and Plant Health Inspection Service, State, or accredited veterinarian[1] is found free of tuberculosis lesions during postmortem inspection.

(d) *Portions of carcasses and carcasses of cattle passed for cooking.* (1) When a cattle carcass reveals a tuberculosis lesion or lesions not so severe or so numerous as the lesions described in paragraph (a) of this section, the unaffected portion of the carcass may be passed for cooking in accordance with part 315 of this chapter; if the character and extent of the lesions indicate a localized condition, and if the lesions are calcified or encapsulated, and provided the affected organ or other part is condemned.

(2) When the carcass of a cattle identified as a reactor to a tuberculin test administered by an Animal and Plant Health Inspection Service, State or accredited veterinarian is found free of lesions of tuberculosis, the carcass may be passed for cooking in accordance with part 315 of this chapter.

(e) *Portions of carcasses and carcasses of swine passed without restriction for human food.* Swine carcasses found free of tuberculosis lesions during post mortem inspection may be passed for human food without restriction. When tuberculosis lesions in any swine carcass are localized and confined to one primary seat of infection, such as the cervical lymph nodes, the mesenteric lymph nodes, or the mediastinal lymph nodes, the unaffected portion of the carcass may be passed for human food without restriction after the affected organ or other part is condemned.

(f) *Portions of carcasses of swine passed for cooking.* When the carcass of any swine reveals lesions more severe or more numerous than those described in paragraph (e) of this section, but not so severe or so numerous as the lesions described in paragraph (a) of this section, the unaffected portions of such carcass may be passed for cooking in accordance with part 315 of this chapter; if the character and extent of the lesions indicate a localized condition, and if the lesions are calcified or encapsulated, and provided the affected organ or other part is condemned.

[1] Such testing is conducted in the tuberculosis eradication program of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

(g) *Carcasses of sheep, goats, and equines passed without restriction for human food.* Carcasses of sheep, goats, and equines may be passed without restriction for human food only if found free of tuberculosis lesions during post mortem inspection.

(h) *Portions of carcasses of sheep, goats, and equines passed for cooking.* If a carcass of any sheep, goat, or equine reveals a tuberculosis lesion or lesions that are not so severe or so numerous as the lesions described in paragraph (a) of this section, the unaffected portion of the carcass may be passed for cooking in accordance with part 315 of this chapter; if the character and extent of the lesions indicate a localized condition, and if the lesions are calcified or encapsulated, and provided the affected organ or other part is condemned.

[37 FR 2661, Feb. 4, 1972; 38 FR 29214, Oct. 23, 1973]

§ 311.3 Hog cholera.

(a) The carcasses of all hogs affected with hog cholera shall be condemned.

(b) Inconclusive but suspicious symptoms of hog cholera observed during the ante-mortem inspection of a U.S. suspect shall be duly considered in connection with post-mortem findings and when the carcass of such a suspect shows lesions in the kidneys and the lymph nodes which resemble lesions of hog cholera, they shall be regarded as those of hog cholera and the carcass shall be condemned.

(c) When lesions resembling those of hog cholera occur in kidneys and lymph nodes of carcasses of hogs which appeared normal on ante-mortem inspection, further inspection of such carcasses shall be made for corroborative lesions. If on such further inspection, characteristic lesions of hog cholera are found in some organ or tissue in addition to those in the kidneys or in the lymph nodes or in both, then all lesions shall be regarded as those of hog cholera and the carcass shall be condemned. Immediate notification shall be given by the inspector to the official in the Veterinary Services unit of the Animal and Plant Health Inspection Service who has responsibility for control of swine diseases in the State where the swine are located.

[35 FR 15569, Oct. 3, 1970, as amended at 40 FR 27225, June 27, 1975]

§ 311.5 Swine erysipelas.

Carcasses affected with swine erysipelas which is acute or generalized, or which show systemic change, shall be condemned.

§ 311.6 Diamond-skin disease.

Carcasses of hogs affected with diamond-skin disease when localized and not associated with systemic change may be passed for human food after removal and condemnation of the affected parts, provided such carcasses are otherwise healthy.

§ 311.7 Arthritis.

(a) Carcasses affected with arthritis which is localized and not associated with systemic change may be passed for human food after removal and condemnation of all affected parts. Affected joints with corresponding lymph nodes shall be removed and condemned. In order to avoid contamination of the meat which is passed, a joint capsule shall not be opened until after the affected joint is removed.

(b) Carcasses affected with arthritis shall be condemned when there is evidence of systemic involvement.

§ 311.8 Cattle carcasses affected with anasarca or generalized edema.

(a) Carcasses of cattle found on post-mortem inspection to be affected with anasarca in advanced stages and characterized by an extensive or well-marked generalized edema shall be condemned.

(b) Carcasses of cattle, including their detached organs and other parts, found on post-mortem inspection to be affected with anasarca to a lesser extent than as described in paragraph (a) of this section may be passed for human food after removal and condemnation of the affected tissues, provided the lesion is localized.

§ 311.9 Actinomycosis and actinobacillosis.

(a) The definition of generalization as outlined for tuberculosis in § 311.2(a)

shall apply for actinomycosis and actinobacillosis, and carcasses of livestock with generalized lesions of either such disease shall be condemned.

(b) Carcasses of livestock in a well-nourished condition showing uncomplicated localized lesions of actinomycosis or actinobacillosis may be passed for human food after the infected organs or other infected parts have been removed and condemned, except as provided in paragraphs (c) and (d) of this section.

(c) Heads affected with actinomycosis or actinobacillosis, including the tongue, shall be condemned, except that when the disease of the jaw is slight, strictly localized, and without suppuration, fistulous tracts, or lymph node involvement, the tongue, if free from disease, may be passed, or, when the disease is slight and confined to the lymph nodes, the head including the tongue, may be passed for human food after the affected nodes have been removed and condemned.

(d) When the disease is slight and confined to the tongue, with or without involvement of the corresponding lymph nodes, the head may be passed for human food after removal and condemnation of the tongue and corresponding lymph nodes.

§ 311.10 Anaplasmosis, anthrax, babesiosis, bacillary hemoglobinuria in cattle, blackleg, bluetongue, hemorrhagic septicemia, icterohematuria in sheep, infectious bovine rhinotracheitis, leptospirosis, malignant epizootic catarrh, strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), infectious anemia (swamp fever), dourine, acute influenza, generalized osteoporosis, glanders (farcy), acute inflammatory lameness, extensive fistula, and unhealed vaccine lesions.

(a) Carcasses of livestock affected with or showing lesions of any of the following named diseases or conditions shall be condemned:

(1) Anthrax.
(2) Blackleg.
(3) Unhealed vaccine lesions (vaccinia).
(4) Strangles.
(5) Purpura hemorrhagica.
(6) Azoturia.
(7) Infectious equine encephalomyelitis.
(8) Toxic encephalomyelitis (forage poisoning).
(9) Infectious anemia (swamp fever).
(10) Dourine.
(11) Acute influenza.
(12) Generalized osteoporosis.
(13) Glanders (farcy).
(14) Acute inflammatory lameness.
(15) Extensive fistula.

(b) Carcasses of livestock affected with or showing lesions of any of the following named diseases or conditions shall be condemned, except when recovery has occurred to the extent that only localized lesions persist, in which case the carcass may be passed for human food after removal and condemnation of the affected organs or other parts:

(1) Anaplasmosis.
(2) Bacillary hemoglobinuria in cattle.
(3) Babesiosis (piroplasmosis).
(4) Bluetongue.
(5) Hemorrhagic septicemia.
(6) Icterohematuria in sheep.
(7) Infectious bovine rhinotracheitis.
(8) Leptospirosis.
(9) Malignant epizootic catarrh.

[35 FR 15569, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971]

§ 311.11 Neoplasms.

(a) An individual organ or other part of a carcass affected with a neoplasm shall be condemned. If there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm, the entire carcass shall be condemned.

(b) Carcasses affected with malignant lymphoma shall be condemned.

§ 311.12 Epithelioma of the eye.

(a) Carcasses of animals affected with epithelioma of the eye, or the orbital region shall be condemned in their entirety if one of the following three conditions exists:

(1) The affection has involved the osseous structures of the head with extensive infection, suppuration, and necrosis;

(2) There is metastasis from the eye, or the orbital region, to any lymph

node including the parotid lymph node, internal organs, muscles, skeleton, or other structures, regardless of the extent of the primary tumor; or

(3) The affection, regardless of extent, is associated with cachexia or evidence of absorption or secondary changes.

(b) Carcasses of animals affected with epithelioma of the eye, or the orbital region, to a lesser extent than as described in paragraph (a) of this section may be passed for human food after removal and condemnation of the head, including the tongue, provided the carcass is otherwise normal.

§ 311.13 Pigmentary conditions; melanosis, xanthosis, ochronosis, etc.

(a) Except as provided in § 311.19, carcasses of livestock showing generalized pigmentary deposits shall be condemned.

(b) The affected parts of carcasses showing localized pigmentary deposits of such character as to be unwholesome or otherwise adulterated shall be removed and condemned.

§ 311.14 Abrasions, bruises, abscesses, pus, etc.

All slight, well-limited abrasions on the tongue and inner surface of the lips and mouth, when without lymph node involvement, shall be carefully excised, leaving only sound, normal tissue, which may be passed for human food. Any organ or other part of a carcass which is badly bruised or which is affected by an abscess, or a suppurating sore shall be condemned; and when the lesions are of such character or extent as to affect the whole carcass, the whole carcass shall be condemned. Portions of carcasses which are contaminated by pus or other diseased material shall be condemned.

§ 311.15 Brucellosis.

Carcasses affected with localized lesions of brucellosis may be passed for human food after the affected parts are removed and condemned.

§ 311.16 Carcasses so infected that consumption of the meat may cause food poisoning.

(a) All carcasses of animals so infected that consumption of the products thereof may give rise to food poisoning shall be condemned. This includes all carcasses showing signs of:

(1) Acute inflammation of the lungs, pleura, pericardium, peritoneum, or meninges.

(2) Septicemia or pyemia, whether puerperal, traumatic, or without any evident cause.

(3) Gangrenous or severe hemorrhagic enteritis or gastritis.

(4) Acute diffuse metritis or mammitis.

(5) Phlebitis of the umbilical veins.

(6) Septic or purulent traumatic pericarditis.

(7) Any acute inflammation, abscess, or suppurating sore, if associated with acute nephritis, fatty and degenerated liver, swollen soft spleen, marked pulmonary hyperemia, general swelling of lymph nodes, diffuse redness of the skin, cachexia, icteric discoloration of the carcass or similar condition, either singly or in combination.

(8) Salmonellosis.

(b) Implements contaminated by contact with carcasses affected with any of the disease conditions mentioned in this section shall be thoroughly cleaned and sanitized as prescribed in part 308 of this subchapter. The equipment used in the dressing of such carcasses, such as viscera trucks or inspection tables, shall be sanitized with hot water having a minimum temperature of 180 °F. Carcasses or parts of carcasses contaminated by contact with such diseased carcasses shall be condemned unless all contaminated tissues are removed within 2 hours.

§ 311.17 Necrobacillosis, pyemia, and septicemia.

From the standpoint of meat inspection, necrobacillosis may be regarded as a local infection at the beginning, and carcasses in which the lesions are localized may be passed for human food if in a good state of nutrition, after those portions affected with necrotic lesions are removed and condemned. However, when emaciation, cloudy swelling of the parenchymatous tissue of organs or enlargement of the lymph nodes is associated with the infection, it is evident that the disease has progressed beyond the condition of localization to a state of toxemia, and the

entire carcass shall therefore be condemned as both unwholesome and noxious. Pyemia or septicemia may intervene as a complication of the local necrosis, and when present the carcass shall be condemned in accordance with § 311.16.

§ 311.18 Caseous lymphadenitis.

(a) A thin carcass showing well-marked lesions in the viscera and the skeletal lymph nodes, or a thin carcass showing extensive lesions in any part shall be condemned.

(b) A thin carcass showing well-marked lesions in the viscera with only slight lesions elsewhere or showing well-marked lesions in the skeletal lymph nodes with only slight lesions elsewhere may be passed for cooking.

(c) A thin carcass showing only slight lesions in the skeletal lymph nodes and in the viscera may be passed for human food without restriction.

(d) A well-nourished carcass showing well-marked lesions in the viscera and with only slight lesions elsewhere or showing well-marked lesions confined to the skeletal lymph nodes with only slight lesions elsewhere may be passed for human food without restriction.

(e) A well-nourished carcass showing well-marked lesions in the viscera and the skeletal lymph nodes may be passed for cooking; but where the lesions in a well-nourished carcass are both numerous and extensive, it shall be condemned.

(f) All affected organs and nodes of carcasses passed for human food without restriction or passed for cooking shall be removed and condemned.

(g) As used in this section, the term ''thin'' does not apply to a carcass which is anemic or emaciated; and the term ''lesions'' refers to lesions of caseous lymphadenitis.

§ 311.19 Icterus.

Carcasses showing any degree of icterus shall be condemned. Yellow fat conditions caused by nutritional factors or characteristic of certain breeds of livestock and yellow fat sometimes seen in sheep shall not be confused with icterus. Such carcasses should be passed for human food, if otherwise normal.

§ 311.20 Sexual odor of swine.

(a) Carcasses of swine which give off a pronounced sexual odor shall be condemned.

(b) The meat of swine carcasses which give off a sexual odor less than pronounced may be passed for use in comminuted cooked meat food product or for rendering. Otherwise it shall be condemned.

§ 311.21 Mange or scab.

Carcasses of livestock affected with mange or scab in advanced stages, showing cachexia or extensive inflammation of the flesh, shall be condemned. When the disease is slight, the carcass may be passed after removal of the affected portion.

§ 311.22 Hogs affected with urticaria, tinea tonsurans, demodex follicurlorum, or erythema.

Carcasses of hogs affected with urticaria (nettle rash), tinea tonsurans, demodex folliculorum, or erythema may be passed for human food after detaching and condemning the affected skin, if the carcass is otherwise not adulterated.

§ 311.23 Tapeworm cysts (cysticercus bovis) in cattle.

(a) Except as provided in paragraph (b) of this section, carcasses of cattle affected with lesions of cysticercus bovis shall be disposed of as follows:

(1) Carcasses of cattle displaying lesions of cysticercus bovis shall be condemned if the infestation is extensive or if the musculature is edematous or discolored. Carcasses shall be considered extensively infested if in addition to finding lesions in at least two of the usual inspection sites, namely the heart, diaphragm and its pillars, muscles of mastication, esophagus, tongue, and musculature exposed during normal dressing operations, they are found in at least two of the sites exposed by (i) an incision made into each round exposing the musculature in cross section, and (ii) a transverse incision into each forelimb commencing 2 or 3 inches above the point of the olecranon and extending to the humerus.

(2) Carcasses of cattle showing one or more tapeworm lesions of cysticercus bovis but not so extensive as indicated

in paragraph (a)(1) of this section, as determined by a careful examination, including examination of, but not limited to, the heart, diaphragm and its pillars, muscles of mastication, esophagus, tongue, and musculature exposed during normal dressing operations, may be passed for human food after removal and condemnation of the lesions with surrounding tissues: *Provided*, That the carcasses, appropriately identified by retained tags, are held in cold storage under positive control of a USDA Food Inspector at a temperature not higher than 15 °F. continuously for a period of not less than 10 days, or in the case of boned meat derived from such carcasses, the meat, when in boxes, tierces, or other containers, appropriately identified by retained tags, is held under positive control of a Program Inspector at a temperature of not higher than 15 °F. continuously for a period of not less than 20 days. As an alternative to retention in cold storage as provided in this subparagraph, such carcasses and meat may be heated throughout to a temperature of at least 140 °F. under positive control of a Program Inspector.

(b) Edible viscera and offal shall be disposed of in the same manner as the rest of the carcass from which they were derived unless any lesion of cysticercus bovis is found in these by-products, in which case they shall be condemned.

[36 FR 4591, Mar. 10, 1971]

§ 311.24 Hogs affected with tapeworm cysts.

Carcasses of hogs affected with tapeworm cysts (Cysticercus cellulosae) may be passed for cooking, unless the infestation is excessive, in which case the carcass shall be condemned.

§ 311.25 Parasites not transmissible to man; tapeworm cysts in sheep; hydatid cysts; flukes; gid bladderworms.

(a) In the disposal of carcasses, edible organs, and other parts of carcasses showing evidence of infestation with parasites not transmissible to man, the following general rules shall govern except as otherwise provided in this section: If the lesions are localized in such manner and are of such character that the parasites and the lesions caused by them can be completely removed, the nonaffected portion of the carcass, organ, or other part of the carcass may be passed for human food after the removal and condemnation of the affected portions. If an organ or other part of a carcass shows numerous lesions caused by parasites, or if the character of the infestation is such that complete extirpation of the parasitic infestation or invasion renders the part in any way unfit for human food, the affected part shall be condemned. If parasites are found to be distributed in a carcass in such a manner or to be of such character that their removal and the removal of the lesions caused by them is impracticable, no part of the carcass shall be passed for human food. If the infestation is excessive, the carcass shall be condemned. If the infestation is moderate, the carcass may be passed for cooking, but in case such carcass is not cooked as required by part 315 of this subchapter, it shall be condemned.

(b) In the case of sheep carcasses affected with tapeworm cysts (Cysticercus ovis, so-called sheep measles, not transmissible to man), such carcasses may be passed for human food after the removal and condemnation of the affected portions: *Provided, however*, That if, upon the final inspection of sheep carcasses retained on account of measles, the total number of cysts found embedded in muscular tissue, or in immediate relation with muscular tissue, excluding the heart, exceeds five, the entire carcass shall be condemned, or such carcass shall be heated throughout to a temperature of at least 140 °F. After removal and condemnation of all affected portions.

(c) Carcasses found infested with gid bladder-worms (Coenurus cerebralis, Multiceps multiceps) may be passed for human food after condemnation of the affected organ (brain or spinal cord).

(d) Organs or other parts of carcasses infested with hydatid cysts (echinococus) shall be condemned.

(e) Livers infested with flukes or fringed tapeworms shall be condemned.

§ 311.26 Emaciation.

Carcasses of livestock too emaciated to produce wholesome meat, and carcasses which show a serous infiltration of muscle tissues, or a serous or mucoid degeneration of the fatty tissue, shall be condemned. A gelatinous change of the fat of the heart and kidneys of well-nourished carcasses and mere leanness shall not be classed as emaciation.

[35 FR 15569, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 311.27 Injured animals slaughtered at unusual hours.

When it is necessary for humane reasons to slaughter an injured animal at night or on Sunday or a holiday when the inspector cannot be obtained, the carcass and all parts of all livestock except for cattle shall be kept for inspection, with the head and all viscera except the stomach, bladder, and intestines held by the natural attachments. If all parts are not so kept for inspection, the carcass shall be condemned. If, on inspection of a carcass slaughtered in the absence of an inspector, any lesion or other evidence is found indicating that the animal was sick or diseased, or affected with any other condition requiring condemnation of the animal on ante-mortem inspection, or if there is lacking evidence of the condition which rendered emergency slaughter necessary, the carcass shall be condemned. The parts and carcasses of cattle slaughtered in the absence of an inspector shall not be used for human food.

[35 FR 15569, Oct. 3, 1970, as amended at 69 FR 1874, Jan. 12, 2004]

§ 311.28 Carcasses of young calves, pigs, kids, lambs, and foals.

Carcasses of young calves, pigs, kids, lambs, and foals are unwholesome and shall be condemned if (a) the meat has the appearance of being water-soaked, is loose, flabby, tears easily, and can be perforated with the fingers; or (b) its color is grayish-red; or (c) good muscular development as a whole is lacking, especially noticeable on the upper shank of the leg, where small amounts of serous infiltrates or small edematous patches are sometimes present between the muscles; or (d) the tissue which later develops as the fat capsule of the kidneys is edematous, dirty yellow, or grayish-red, tough, and intermixed with islands of fat.

§ 311.29 Unborn and stillborn animals.

All unborn and stillborn animals shall be condemned and no hide or skin thereof shall be removed from the carcass within a room in which edible products are handled.

§ 311.30 Livestock suffocated and hogs scalded alive.

All livestock which have been suffocated in any way and hogs which have entered the scalding vat alive shall be condemned.

§ 311.31 Livers affected with carotenosis; livers designated as "telangiectatic," "sawdust," or "spotted."

(a) Livers affected with carotenosis shall be condemned.

(b) Cattle livers and calf livers showing the conditions sometimes designated as ''telangiectatic,'' ''sawdust,'' or ''spotted'' shall be disposed of as follows:

(1) When any or all of the conditions are slight in the organ, the whole organ shall be passed for human food without restriction.

(2) When any or all of the conditions are more severe than slight and involve less than one-half of the organ, while in the remainder of the organ the conditions are slight or nonexistent, the remainder shall be passed for human food without restriction and the other portion shall be condemned.

(3) When any or all of the conditions are more severe than slight and involve one-half or more of the organ, the whole organ shall be condemned.

(4) The divisions of an organ into two parts as contemplated in this paragraph for disposition, shall be accomplished by one cut through the organ. This, of course, does not prohibit incisions which are necessary for inspection.

(c) ''Telangiectatic,'' ''sawdust,'' or ''spotted'' livers and parts of livers which are condemned for human food may be shipped from an official establishment for purposes other than

human food in accordance with § 314.10 of this subchapter.

§ 311.32 Vesicular diseases.

(a) Any carcass affected with vesicular disease shall be condemned if the condition is acute and if the extent of the condition is such that it affects the entire carcass or there is evidence of absorption or secondary change.

(b) Any carcass affected with vesicular disease to a lesser extent than as described in paragraph (a) of this section may be passed for human food after removal and condemnation of the affected parts, if the carcass is otherwise healthy.

§ 311.33 Listeriosis.

Carcasses of livestock identified as U.S. Suspects because of a history of listeriosis shall be passed for human food after condemnation of the head if the carcass is otherwise normal.

§ 311.34 Anemia.

Carcasses of livestock too anemic to produce wholesome meat shall be condemned.

§ 311.35 Muscular inflammation, degeneration, or infiltration.

(a) If muscular lesions are found to be distributed in such a manner or to be of such character that removal is impractical, the carcass shall be condemned.

(b) If muscular lesions are found to be distributed in such a manner or to be of such character that removal is practical, the following rules shall govern the disposal of the carcasses, edible organs, and other parts of carcasses showing such muscular lesions. If the lesions are localized in such a manner and are of such a character that the affected tissues can be removed, the nonaffected parts of the carcass may be passed for human food after the removal and condemnation of the affected portion. If a part of the carcass shows numerous lesions, or if the character of the lesion is such that complete extirpation is difficult and uncertainly accomplished, or if the lesion renders the part in any way unfit for human food, the part shall be condemned.

(c) If the lesions are slight or of such character as to be insignificant from a standpoint of wholesomeness, the carcass or parts may be passed for use in the manufacture of comminuted cooked product, after removal and condemnation of the visibly affected portions.

§ 311.36 Coccidioidal granuloma.

(a) Carcasses which are affected with generalized coccidioidal granuloma or which show systemic changes because of such disease shall be condemned.

(b) Carcasses affected with localized lesions of this disease may be passed for human food after the affected parts are removed and condemned.

§ 311.37 Odors, foreign and urine.

(a) Carcasses which give off a pronounced odor of medicinal, chemical, or other foreign substance shall be condemned.

(b) Carcasses which give off a pronounced urine odor shall be condemned.

(c) Carcasses, organs, or parts affected by odor to a lesser degree than as described in paragraphs (a) and (b) of this section and in which the odor can be removed by trimming or chilling may be passed for human food, after removal of affected parts or dissipation of the condition.

§ 311.38 Meat and meat byproducts from livestock which have been exposed to radiation.

Meat and meat byproducts from livestock which have been administered radioactive material shall be condemned unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

§ 311.39 Biological residues.

Carcasses, organs, or other parts of carcasses of livestock shall be condemned if it is determined that they are adulterated because of the presence of any biological residues.

PART 312—OFFICIAL MARKS, DEVICES AND CERTIFICATES

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15573, Oct. 3, 1970, unless otherwise noted.

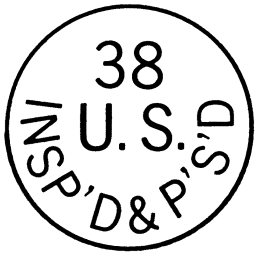
§ 312.1 General.

The marks, devices, and certificates prescribed or referenced in this part shall be official marks, devices, and certificates for purposes of the Act, and shall be used in accordance with the provisions of this part and the regulations cited therein.

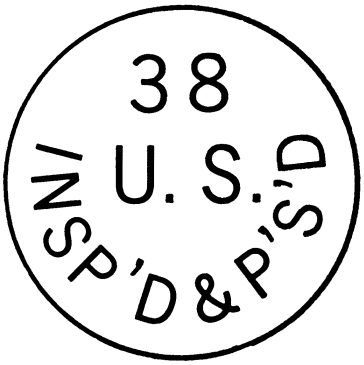
§ 312.2 Official marks and devices to identify inspected and passed products of cattle, sheep, swine, or goats.

(a) The official inspection legend required by part 316 of this subchapter to be applied to inspected and passed carcasses and parts of carcasses of cattle, sheep, swine and goats, meat food products in animal casings, and other products as approved by the Administrator, shall be in the appropriate form as hereinafter specified: [1]

For application to sheep carcasses, the loins and ribs of pork, beef tails, and the smaller varieties of sausage and meat food products in animal casings.



For application to calf and goat carcasses and on the larger varieties of sausage and meat food products in animal casings.



For application to beef and hog carcasses primal parts and cuts therefrom, beef livers, beef tongues, beef hearts, and smoked meats not in casings.

[1] The number ''38'' is given as an example only. The establishment number of the official establishment where the product is prepared shall be used in lieu thereof.

For application to burlap, muslin, cheesecloth, heavy paper, or other acceptable material that encloses carcasses or parts of carcasses.

(b)(1) The official inspection legend required by part 317 of this subchapter to be shown on all labels for inspected and passed products of cattle, sheep, swine, and goats shall be in the following form [1] except that it need not be of the size illustrated, provided that it is a sufficient size and of such color as to be conspicuously displayed and readily legible and the same proportions of letter size and boldness are maintained as illustrated:

(2) This official mark shall be applied by mechanical means and shall not be applied by a hand stamp.

(3) The official inspection legend described in paragraph (b)(1) of this section may also be used for purposes of part 316 of this subchapter on shipping containers, band labels, artificial casings, and other articles with the approval of the Administrator.

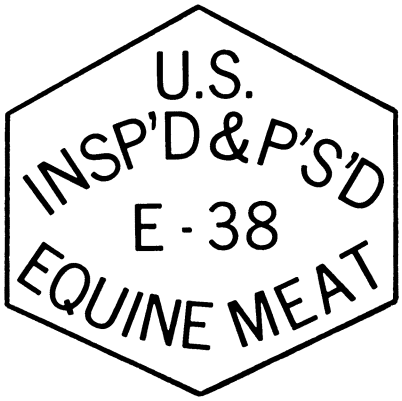
(c) Any brand, stamp, label, or other device approved by the Administrator and bearing any official mark prescribed in paragraphs (a) or (b) of this section shall be an official device for purposes of the Act.

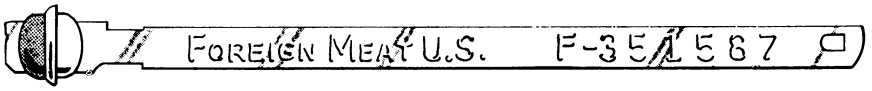
[35 FR 15573, Oct. 3, 1970; 36 FR 12002, June 24, 1971]

§ 312.3 Official marks and devices to identify inspected and passed equine products.

(a) The official inspection legend required by § 316.12 or § 317.2 of this subchapter to identify inspected and passed horse carcasses and parts of carcasses, or horse meat food products shall be in the appropriate form as hereinafter specified: [1]

(b) The official inspection legend required by §316.12 or §317.2 of this subchapter to identify inspected and passed mule and other (nonhorse) equine carcasses and parts of carcasses, or equine meat food products shall be in whichever of the following form, is appropriate:[1]





(c) Any brand, stamp, label, or other device approved by the Administrator and bearing any official mark prescribed in paragraphs (a) or (b) of this section shall be an official device for purposes of the Act.

§312.4 Official ante-mortem inspection marks and devices.

The official marks and devices used in connection with ante-mortem inspection are those prescribed in §309.18 of this subchapter.

§312.5 Official seals for transportation of products.

The official mark for use in sealing railroad cars or other means of conveyance as prescribed in part 325 of this subchapter shall be the inscription and a serial number as hereinafter shown[2] and any seal approved by the Administrator for applying such mark shall be an official device for purposes of the Act. This seal shall be attached to the means of conveyance only by a Program employee and he shall also affix thereto a ''Warning Tag'' (Form MP–408–3).

[35 FR 15573, Oct. 3, 1970, as amended at 39 FR 36000, Oct. 7, 1974; 51 FR 37707, Oct. 24, 1986]

[1]The number ''38'' is given as an example only. The establishment number of the official establishment where the product is prepared shall be used in lieu thereof.

[2]The number ''2135202'' is given as an example only. The serial number of the specific seal will be shown in lieu thereof.

§ 312.6 Official marks and devices in connection with post-mortem inspection and identification of adulterated products and insanitary equipment and facilities.

(a) The official marks required by parts 310 and 416 of this chapter for use in post-mortem inspection and identification of adulterated products and insanitary equipment and facilities are:

(1) The tag (Form MP–427) which is used to retain carcasses and parts of carcasses in the slaughter department; it is black and white, and bears the legend ''U.S. Retained.''

(2) The ''U.S. Retained'' mark which is applied to products and articles as prescribed in part 310 of this subchapter by means of a paper tag (Form MP–35) bearing the legend ''U.S. Retained.''

(3) The ''U.S. Rejected'' mark which is used to identify insanitary buildings, rooms, or equipment as prescribed in part 416, section 6, of this chapter and is applied by means of a paper tag (Form MP–35) bearing the legend ''U.S. Rejected.''

(4) The ''U.S. Passed for Cooking'' mark is applied on products passed for cooking as prescribed in part 310 of this subchapter by means of a brand and is in the following form:

U.S. PASSED FOR COOKING

(5) The ''U.S. Inspected and Condemned'' mark shall be applied to products condemned as prescribed in part 310 by means of a brand and is in the following form:

U.S. INSP'D AND CONDEMNED

(b) The ''U.S. Retained'' and ''U.S. Rejected'' tags, and all other brands, stamps, labels, and other devices approved by the Administrator and bearing any official mark prescribed in paragraph (a) of this section, shall be official devices for purposes of the Act.

[35 FR 15573, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973; 39 FR 36000; Oct. 7, 1974; 43 FR 29268, July 7, 1978; 64 FR 36415, Oct. 20, 1999; 65 FR 2284, Jan. 14, 2000]

§ 312.7 [Reserved]

§ 312.8 Export inspection marks.

The export inspection mark required in § 322.1 of this chapter must be either a mark that contains a unique identifier that links the consignment to the export certificate or an official mark with the following form:[1]

[81 FR 42233, June 29, 2016]

§ 312.9 Official detention marks and devices.

The official mark for articles and livestock detained under part 329 of this subchapter shall be the designation ''U.S. Detained'' and the official device for applying such mark shall be the official ''U.S. Detained'' tag (FSIS Form 8400–2) as prescribed in § 329.2 of this subchapter.

[55 FR 47842, Nov. 16, 1990]

§ 312.10 Official mark for maintaining the identity and integrity of samples.

The official mark for use in sealing containers of samples submitted under any requirements in this subchapter and section 202 of the Federal Meat Inspection Act shall bear the designation ''Sample Seal'' accompanied by the official USDA logo as shown below. Any seal approved by the Administrator for applying such mark shall be deemed an official device for purposes of the Act.

[1] The number ''1234567'' is given as an example only. The number on the mark will correspond to the printed number on the export certificate.

Such device shall be supplied to inspectors, compliance officers, and other designated Agency officials by the United States Department of Agriculture.

[52 FR 41958, Nov. 2, 1987]

PART 313—HUMANE SLAUGHTER OF LIVESTOCK

Sec.

AUTHORITY: 7 U.S.C. 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 44 FR 68813, Nov. 30, 1979, unless otherwise noted.

§ 313.1 Livestock pens, driveways and ramps.

(a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking, and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.

(b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable construction and maintenance.

(c) U.S. Suspects (as defined in §301.2(xxx)) and dying, diseased, and disabled livestock (as defined in §301.2(y)) shall be provided with a covered pen sufficient, in the opinion of the inspector, to protect them from the adverse climatic conditions of the locale while awaiting disposition by the inspector.

(d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.

[44 FR 68813, Nov. 30, 1979, as amended at 53 FR 49848, Dec. 12, 1988]

§ 313.2 Handling of livestock.

(a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.

(b) Electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement and injury. Any use of such implements which, in the opinion of the inspector, is excessive, is prohibited. Electrical prods attached to AC house current shall be reduced by a transformer to the lowest effective voltage not to exceed 50 volts AC.

(c) Pipes, sharp or pointed objects, and other items which, in the opinion of the inspector, would cause injury or unnecessary pain to the animal shall not be used to drive livestock.

(d) Disabled livestock and other animals unable to move.

(1) Disabled animals and other animals unable to move shall be separated from normal ambulatory animals and placed in the covered pen provided for in §313.1(c).

(2) The dragging of disabled animals and other animals unable to move, while conscious, is prohibited. Stunned animals may, however, be dragged.

(3) Disabled animals and other animals unable to move may be moved, while conscious, on equipment suitable for such purposes; e.g., stone boats.

(e) Animals shall have access to water in all holding pens and, if held longer than 24 hours, access to feed.

There shall be sufficient room in the holding pen for animals held overnight to lie down.

(f) Stunning methods approved in § 313.30 shall be effectively applied to animals prior to their being shackled, hoisted, thrown, cast, or cut.

§ 313.5 Chemical; carbon dioxide.

The slaughtering of sheep, calves and swine with the use of carbon dioxide gas and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Administration of gas, required effect; handling.* (1) The carbon dioxide gas shall be administered in a chamber in accordance with this section so as to produce surgical anesthesia in the animals before they are shackled, hoisted, thrown, cast, or cut. The animals shall be exposed to the carbon dioxide gas in a way that will accomplish the anesthesia quickly and calmly, with a minimum of excitement and discomfort to the animals. In swine, carbon dioxide may be administered to induce death in the animals before they are shackled, hoisted, thrown, cast, or cut.

(2) The driving or conveying of the animals to the carbon dioxide chamber shall be done with a minimum of excitement and discomfort to the animals. Delivery of calm animals to the anesthesia chamber is essential since the induction, or early phase, of anesthesia is less violent with docile animals. Among other things this requires that, in driving animals to the anesthesia chamber, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) On emerging from the carbon dioxide tunnel, the animals shall be in a state of surgical anesthesia and shall remain in this condition throughout shackling, sticking, and bleeding, except for swine in which death has been induced by the administration of carbon dioxide. Asphyxia or death from any cause shall not be produced in animals before bleeding, except for swine in which death has been induced by the administration of carbon dioxide.

(b) *Facilities and procedures*—(1) *General requirements for gas chambers and auxiliary equipment; operator.* (i) The carbon dioxide gas shall be administered in a tunnel which is designed to permit the effective exposure of the animal. Two types of tunnels, based on the same principle, are in common use for carbon dioxide anesthesia. They are the ''U'' type tunnel and the ''Straight Line'' type tunnel, and are based on the principle that carbon dioxide gas has a higher specific gravity than air. The tunnels are open at both ends for entry and exit of animals and have a depressed central section. Anesthetizing, or, in the case of swine, death-inducing, carbon dioxide concentrations are maintained in the central sections of the tunnels. Effective anaesthetization is produced in these central sections. Animals are driven from holding pens through pathways constructed of large-diameter pipe or smooth metal and onto continuous conveyor devices that move the animals through the tunnels. The animals are either compartmentalized on the conveyors by mechanical impellers synchronized with the conveyor or they are otherwise prevented from crowding. While impellers are used to compartmentalize the animals, mechanically or manually operated gates are used to move the animals onto the conveyors. Surgically anaesthetized animals, or killed swine, are moved out of the tunnels by the same continuous conveyors that moved them into and through the carbon dioxide gas.

(ii) Flow of animals into and through the carbon dioxide chamber is dependent on one operator. The operation or stoppage of the conveyor is entirely dependent upon this operator. It is necessary that he be skilled, attentive, and aware of his responsibility. Overdosages and death of animals can be brought about by carelessness of this individual.

(2) *Special requirements for gas chamber and auxiliary equipment.* The ability of anesthetizing equipment to perform with maximum efficiency is dependent on its proper design and efficient mechanical operation. Pathways, compartments, gas chambers, and all other equipment used must be designed to accommodate properly the species of animals being anesthetized. They shall be free from pain-producing restraining

devices. Injury of animals must be prevented by the elimination of sharp projections or exposed wheels or gears. There shall be no unnecessary holes, spaces or openings where feet or legs of animals may be injured. Impellers or other devices designed to mechanically move or drive animals or otherwise keep them in motion or compartmentalized shall be constructed of flexible or well padded rigid material. Power activated gates designed for constant flow of animals to anesthetizing equipment shall be so fabricated that they will not cause injury. All equipment involved in anesthetizing animals shall be maintained in good repair.

(3) *Gas.* Maintenance of a uniform carbon dioxide concentration and distribution in the anesthesia chamber is a vital aspect of producing surgical anesthesia. This may be assured by reasonably accurate instruments which sample and analyze carbon dioxide gas concentration within the chamber throughout anesthetizing operations. Gas concentration shall be maintained uniform so that the degree of anesthesia in exposed animals will be constant. Carbon dioxide gas supplied to anesthesia chambers may be from controlled reduction of solid carbon dioxide or from a controlled liquid source. In either case the carbon dioxide shall be supplied at a rate sufficient to anesthetize adequately and uniformly the number of animals passing through the chamber. Sampling of gas for analysis shall be made from a representative place or places within the chamber and on a continuing basis. Gas concentrations and exposure time shall be graphically recorded throughout each day's operation. Neither carbon dioxide nor atmospheric air used in the anesthesia chambers shall contain noxious or irritating gases. Each day before equipment is used for anesthetizing animals, proper care shall be taken to mix adequately the gas and air within the chamber. All gas producing and control equipment shall be maintained in good repair and all indicators, instruments, and measuring devices must be available for inspection by Program inspectors during anesthetizing operations and at other times. An exhaust system must be provided so that, in case of equipment failure, non-uniform carbon dioxide concentrations in the gas tunnel or contamination of the ambient air of the establishment will be prevented.

[44 FR 68813, Nov. 30, 1979, as amended at 59 FR 21640, Apr. 26, 1994]

§ 313.15 Mechanical; captive bolt.

The slaughtering of sheep, swine, goats, calves, cattle, horses, mules, and other equines by using captive bolt stunners and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Application of stunners, required effect; handling.* (1) The captive bolt stunners shall be applied to the livestock in accordance with this section so as to produce immediate unconsciousness in the animals before they are shackled, hoisted, thrown, cast, or cut. The animals shall be stunned in such a manner that they will be rendered unconscious with a minimum of excitement and discomfort.

(2) The driving of the animals to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Delivery of calm animals to the stunning areas is essential since accurate placement of stunning equipment is difficult on nervous or injured animals. Among other things, this requires that, in driving animals to the stunning areas, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) Immediately after the stunning blow is delivered the animals shall be in a state of complete unconsciousness and remain in this condition throughout shackling, sticking and bleeding.

(b) *Facilities and procedures*—(1) *General requirements for stunning facilities; operator.* (i) Acceptable captive bolt stunning instruments may be either skull penetrating or nonpenetrating. The latter type is also described as a concussion or mushroom type stunner. Penetrating instruments on detonation deliver bolts of varying diameters and lengths through the skull and into the brain. Unconsciousness is produced immediately by physical brain destruction and a combination of changes in

intracranial pressure and acceleration concussion. Nonpenetrating or mushroom stunners on detonation deliver a bolt with a flattened circular head against the external surface of the animal's head over the brain. Diameter of the striking surface of the stunner may vary as conditions require. Unconsciousness is produced immediately by a combination of acceleration concussion and changes in intracranial pressures. A combination instrument utilizing both penetrating and nonpenetrating principles is acceptable. Energizing of instruments may be accomplished by detonation of measured charges of gunpowder or accurately controlled compressed air. Captive bolts shall be of such size and design that, when properly positioned and activated, immediate unconsciousness is produced.

(ii) To assure uniform unconsciousness with every blow, compressed air devices must be equipped to deliver the necessary constant air pressure and must have accurate, constantly operating air pressure gauges. Gauges must be easily read and conveniently located for use by the stunning operator and the inspector. For purposes of protecting employees, inspectors, and others, it is desirable that any stunning device be equipped with safety features to prevent injuries from accidental discharge. Stunning instruments must be maintained in good repair.

(iii) The stunning area shall be so designed and constructed as to limit the free movements of animals sufficiently to allow the operator to locate the stunning blow with a high degree of accuracy. All chutes, alleys, gates and restraining mechanisms between and including holding pens and stunning areas shall be free from pain-producing features such as exposed bolt ends, loose boards, splintered or broken planking, and protruding sharp metal of any kind. There shall be no unnecessary holes or other openings where feet or legs of animals may be injured. Overhead drop gates shall be suitably covered on the bottom edge to prevent injury on contact with animals. Roughened or cleated cement shall be used as flooring in chutes leading to stunning areas to reduce falls of animals. Chutes, alleys, and stunning areas shall be so designed that they will comfortably accommodate the kinds of animals to be stunned.

(iv) The stunning operation is an exacting procedure and requires a well-trained and experienced operator. He must be able to accurately place the stunning instrument to produce immediate unconsciousness. He must use the correct detonating charge with regard to kind, breed, size, age, and sex of the animal to produce the desired results.

(2) *Special requirements and prohibitions.* (i) Choice of instrument and force required to produce immediate unconsciousness varies, depending on kind, breed, size, age, and sex of the animal. Young swine, lambs, and calves usually require less stunning force than mature animals of the same kind. Bulls, rams, and boars usually require skull penetration to produce immediate unconsciousness. Charges suitable for smaller kinds of livestock such as swine or for young animals are not acceptably interchanged for use on larger kinds or older livestock, respectively.

(ii) Captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle.

[44 FR 68813, Nov. 30, 1979, as amended at 69 FR 1891, Jan. 12, 2004]

§ 313.16 Mechanical; gunshot.

The slaughtering of cattle, calves, sheep, swine, goats, horses, mules, and other equines by shooting with firearms and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Utilization of firearms, required effect; handling.* (1) The firearms shall be employed in the delivery of a bullet or projectile into the animal in accordance with this section so as to produce immediate unconsciousness in the animal by a single shot before it is shackled, hoisted, thrown, cast, or cut. The animal shall be shot in such a manner that they will be rendered unconscious with a minimum of excitement and discomfort.

(2) The driving of the animals to the shooting areas shall be done with a

minimum of excitement and discomfort to the animals. Delivery of calm animals to the shooting area is essential since accurate placement of the bullet is difficult in case of nervous or injured animals. Among other things, this requires that, in driving animals to the shooting areas, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) Immediately after the firearm is discharged and the projectile is delivered, the animal shall be in a state of complete unconsciousness and remain in this condition throughout shackling, sticking and bleeding.

(b) *Facilities and procedure*—(1) *General requirements for shooting facilities; operator*. (i) On discharge, acceptable firearms dispatch free projectiles or bullets of varying sizes and diameters through the skull and into the brain. Unconsciousness is produced immediately by a combination of physical brain destruction and changes in intracranial pressure. Caliber of firearms shall be such that when properly aimed and discharged, the projectile produces immediate unconsciousness.

(ii) To assure uniform unconsciousness of the animal with every discharge where small-bore firearms are employed, it is necessary to use one of the following type projectiles: Hollow pointed bullets; frangible iron plastic composition bullets; or powdered iron missiles. When powdered iron missiles are used, the firearms shall be in close proximity with the skull of the animal when fired. Firearms must be maintained in good repair. For purposes of protecting employees, inspectors and others, it is desirable that all firearms be equipped with safety devices to prevent injuries from accidental discharge. Aiming and discharging of firearms should be directed away from operating areas.

(iii) The provisions contained in § 313.15(b)(1)(iii) with respect to the stunning area also apply to the shooting area.

(iv) The shooting operation is an exacting procedure and requires a well-trained and experienced operator. He must be able to accurately direct the projectile to produce immediate unconsciousness. He must use the correct caliber firearm, powder charge and type of ammunition to produce the desired results.

(2) *Special requirements*. Choice of firearms and ammunition with respect to caliber and choice of powder charge required to produce immediate unconsciousness of the animal may vary depending on age and sex of the animal. In the case of bulls, rams, and boars, small bore firearms may be used provided they are able to produce immediate unconsciousness of the animals. Small bore firearms are usually effective for stunning other cattle, sheep, swine, and goats, and calves, horses, and mules.

§ 313.30 Electrical; stunning or slaughtering with electric current.

The slaughtering of swine, sheep, calves, cattle, and goats with the use of electric current and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Administration of electric current, required effect; handling*. (1) The electric current shall be administered so as to produce, at a minimum, surgical anesthesia, i.e., a state where the animal feels no painful sensation. The animals shall be either stunned or killed before they are shackled, hoisted, thrown, cast, or cut. They shall be exposed to the electric current in a way that will accomplish the desired result quickly and effectively, with a minimum of excitement and discomfort.

(2) The driving or conveying of the animals to the place of application of electric current shall be done with a minimum of excitement and discomfort to the animals. Delivery of calm animals to the place of application is essential to ensure rapid and effective insensibility. Among other things, this requires that, in driving animals to the place of application, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) The quality and location of the electrical shock shall be such as to produce immediate insensibility to pain in the exposed animal.

(4) The stunned animal shall remain in a state of surgical anesthesia

through shackling, sticking, and bleeding.

(b) *Facilities and procedures; operator*—(1) *General requirements for operator.* It is necessary that the operator of electric current application equipment be skilled, attentive, and aware of his or her responsibility.

(2) *Special requirements for electric current application equipment.* The ability of electric current equipment to perform with maximum efficiency is dependent on its proper design and efficient mechanical operation. Pathways, compartments, current applicators, and all other equipment used must be designed to properly accommodate the species of animals being anesthetized. Animals shall be free from pain-producing restraining devices. Injury of animals must be prevented by the elimination of sharp projections or exposed wheels or gears. There shall be no unnecessary holes, spaces or openings where feet or legs of animals may be injured. Impellers or other devices designed to mechanically move or drive animals or otherwise keep them in motion or compartmentalized shall be constructed of flexible or padded material. Power activated gates designed for constant flow of animals shall be so fabricated that they will not cause injury. All equipment used to apply and control the electrical current shall be maintained in good repair, and all indicators, instruments, and measuring devices shall be available for inspection by Program inspectors during the operation and at other times.

(3) *Electric current.* Each animal shall be given a sufficient application of electric current to ensure surgical anesthesia throughout the bleeding operation. Suitable timing, voltage and current control devices shall be used to ensure that each animal receives the necessary electrical charge to produce immediate unconsciousness. The current shall be applied so as to avoid the production of hemorrhages or other tissue changes which could interfere with inspection procedures.

[44 FR 68813, Nov. 30, 1979, as amended at 50 FR 25202, June 18, 1985]

§ 313.50 Tagging of equipment, alleyways, pens, or compartments to prevent inhumane slaughter or handling in connection with slaughter.

When an inspector observes an incident of inhumane slaughter or handling in connection with slaughter, he/she shall inform the establishment operator of the incident and request that the operator take the necessary steps to prevent a recurrence. If the establishment operator fails to take such action or fails to promptly provide the inspector with satisfactory assurances that such action will be taken, the inspector shall follow the procedures specified in paragraph (a), (b), or (c) of this section, as appropriate.

(a) If the cause of inhumane treatment is the result of facility deficiencies, disrepair, or equipment breakdown, the inspector shall attach a ''U.S. Rejected'' tag thereto. No equipment, alleyway, pen or compartment so tagged shall be used until made acceptable to the inspector. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to such tagging may be dressed, processed, or prepared under inspection.

(b) If the cause of inhumane treatment is the result of establishment employee actions in the handling or moving of livestock, the inspector shall attach a ''U.S. Rejected'' tag to the alleyways leading to the stunning area. After the tagging of the alleyway, no more livestock shall be moved to the stunning area until the inspector receives satisfactory assurances from the establishment operator that there will not be a recurrence. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to the tagging may be dressed, processed, or prepared under inspection.

(c) If the cause of inhumane treatment is the result of improper stunning, the inspector shall attach a ''U.S. Rejected'' tag to the stunning area. Stunning procedures shall not be resumed until the inspector receives satisfactory assurances from the establishment operator that there will not be a recurrence. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior

to such tagging may be dressed, processed, or prepared under inspection.

§ 313.90 [Reserved]

PART 314—HANDLING AND DISPOSAL OF CONDEMNED OR OTHER INEDIBLE PRODUCTS AT OFFICIAL ESTABLISHMENTS

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15575, Oct. 3, 1970, unless otherwise noted.

§ 314.1 Disposition of condemned products at official establishments having tanking facilities; sealing of tanks.

(a) Carcasses, parts of carcasses, and other products condemned at official establishments having facilities for tanking shall, except as provided in paragraph (c) of this section or elsewhere in this part, be disposed of by tanking as follows:

(1) The lower opening of the tank shall first be sealed securely by a Program employee, except when permanently connected with a blow line; then the condemned products shall be placed in the tank in his presence, after which the upper opening shall also be sealed securely by such employee, who shall then see that the contents of the tank are subjected to sufficient heating for sufficient time to effectively destroy the contents for human food purposes.

(2) The use of equipment such as crushers or hashers for pretanking preparation of condemned products in the inedible products department has been found to give inedible character and appearance to the material. Accordingly, if condemned products are so crushed or hashed, conveying systems, rendering tanks, and other equipment used in the further handling of crushed or hashed material need not be locked or sealed during the tanking operations. If the rendering tanks or other equipment contain condemned material not so crushed or hashed, the equipment shall be sealed as prescribed in paragraph (a)(1) of this section. If the crushed or hashed material is not rendered in the establishment where produced, it shall be denatured as provided for in § 314.3 before leaving such establishment.

(b) The seals of tanks shall be broken only by a Program employee and only after the contents of the tanks have been treated as provided in paragraph (a) of this section. The rendered fat derived from condemned material shall be held until a Program employee shall have had an opportunity to determine whether it conforms with the requirements of this section. Samples shall be taken by Program employees as often as is necessary to determine whether the rendered fat is effectually denatured.

(c) Carcasses of animals condemned under § 309.3 of this subchapter may be disposed of as provided in § 314.3, in lieu of tanking, with the approval of the inspector.

§ 314.2 Tanking and other facilities for inedible products to be separate from edible product facilities.

All tanks and equipment used for rendering, otherwise preparing, or storing inedible products must be in rooms or compartments separate from those used for preparing or storing edible products. There may be a connection between rooms or compartments containing inedible products and those containing edible products as long as it

does not cause the adulteration of edible product or create insanitary conditions.

[64 FR 56416, Oct. 20, 1999]

§ 314.3 Disposition of condemned products at official establishments having no tanking facilities.

(a) Carcasses, parts of carcasses, and other products condemned at an official establishment which has no facilities for tanking shall, except as provided in paragraph (b) of this section or elsewhere in this part, be destroyed in the presence of an inspector by incineration, or denatured with crude carbolic acid, or cresylic disinfectant, or a formula consisting of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella or any other proprietary material approved by the Administrator in specific cases. When such product is to be denatured, it shall be freely slashed before the denaturing agent is applied, except that, in the case of dead animals that have not been dressed, the denaturant may be applied by injection. The denaturant must be deposited in all portions of the carcass or product to the extent necessary to preclude its use for food purposes.

(b) All carcasses and parts condemned on account of anthrax, as identified in §310.9(b) of this subchapter, at official establishments which are not equipped with tanking facilities shall be disposed of by (1) complete incineration, or (2) by thorough denaturing with crude carbolic acid, or cresylic disinfectant, and then disposed of in accordance with the requirements of the particular State or municipal authorities, who shall be notified immediately by the area supervisor.

§ 314.4 Suppression of odors in preparing inedible products.

Tanks, fertilizer driers, and other equipment used in the preparation of inedible product must be operated in a manner that will suppress odors incident to such preparation which could adulterate edible product or create insanitary conditions.

[64 FR 56416, Oct. 20, 1999]

§ 314.5 Inedible rendered fats prepared at official establishments.

Except as provided in §325.11(b) of this subchapter, rendered animal fat derived from condemned or other inedible materials at official establishments shall be denatured to effectually distinguish it from an edible product, either with low grade offal during the rendering or by adding to, and mixing thoroughly with, such fat, denaturing oil, No. 2 fuel oil, or brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, and may be shipped in commerce in accordance with §325.11(c) of this subchapter.

[35 FR 15575, Oct. 3, 1970, as amended at 53 FR 24679, June 30, 1988]

§ 314.6 Inedible fats from outside official establishments.

Except as provided in §325.11(b) of this subchapter, inedible fats from outside the premises of any official establishment shall not be received into an official establishment except into the tank room provided for inedible products, and then only when they have been denatured in accordance with §314.5 and are marked in accordance with §316.15 of this subchapter, and when their receipt into the tank room produces no insanitary condition on the premises; nor shall such fats be received in such volume as interferes with prompt disposal of condemned or other inedible material produced at the establishment. When received, they shall not enter any room or compartment used for edible products.

[35 FR 15575, Oct. 3, 1970, as amended at 53 FR 24679, June 30, 1988]

§ 314.7 Carcasses of livestock condemned on ante-mortem inspection not to pass through edible product areas.

Carcasses of livestock which have been condemned on ante-mortem inspection shall not be taken through rooms or compartments in which an edible product is prepared, handled, or stored.

§ 314.8 Dead animal carcasses.

(a) With the exception of dead livestock which have died en route and are received with livestock for slaughter at

an official establishment, no dead animal or part of the carcass of any livestock that died otherwise than by slaughter may be brought on the premises of an official establishment unless advance permission therefore is obtained from the circuit supervisor.

(b) Under no circumstances shall the carcasses of any animal which has died otherwise than by slaughter, or any part thereof, be brought into any room or compartment in which any edible product is prepared, handled, or stored.

§ 314.9 Specimens for educational, research, and other nonfood purposes; permits for, required.

(a) Specimens of condemned or other inedible materials, including embryos and specimens of animal parasites, may be released for educational, research, or other nonfood purposes under permit issued by the inspector in charge: *Provided*, That the person desiring such specimens makes a written application to the inspector in charge for such permit on Form MP–403–10 and arranges with and receives permission from the official establishment to obtain the specimens. Permits shall be issued for a period not longer than 1 year. The permit may be revoked by the inspector in charge if the specimens are not used as stated in the application, or if the collection or handling of the specimens interferes with inspection or the maintenance of sanitary conditions in the establishment.

(b) The specimens referred to in paragraph (a) of this section shall be collected and handled only at such time and place and in such manner as not to interfere with the inspection or to cause any objectionable condition and shall be identified as inedible when they leave the establishment.

[35 FR 15575, Oct. 3, 1970, as amended at 38 FR 18665, July 13, 1973; 39 FR 36000, Oct. 7, 1974]

§ 314.10 Livers condemned because of parasitic infestation and for other causes; conditions for disposal for purposes other than human food.

(a) Livers condemned on account of hydatid cysts shall be disposed of by tanking pursuant to the provisions of § 314.1 of this subchapter if condemned at official establishments having facilities for tanking; otherwise they shall be destroyed pursuant to the provisions of § 314.3 of this subchapter.

(b) Livers condemned because of parasites other than hydatid cysts; and livers condemned because of telangiectasis, angioma, ''sawdust'' condition, cirrhosis, carotenosis, or other nonmalignant change, benign abscesses, or contamination, when these conditions are not associated with infectious diseases in the carcasses, may be shipped from an official establishment only for purposes other than human food, and only if all tissue affected with abscesses is removed and destroyed within the establishment, and all livers are processed and denatured, with any agent prescribed in § 325.13(a)(1) or (2) or (5), and in accordance with § 325.13(a)(6) of this subchapter. This provision for movement from an official establishment is made solely under the Federal Meat Inspection Act and is not intended to relieve or modify any other applicable requirements under any other law regarding the movement of such articles, for purposes other than use as human food.

(c) Livers condemned because of conditions described in paragraph (b) of this section shall be in containers plainly marked ''inedible''.

[41 FR 23701, June 11, 1976]

§ 314.11 Handling of certain condemned products for purposes other than human food.

Condemned carcasses of animals affected with one or more of the following conditions may be shipped from an official establishment only for purposes other than human food and only if permission therefor is obtained from the circuit supervisor: Anasarca, Ocular Squamous Cell Carcinoma (after removal of neoplastic tissue), emaciation, eosinophilic myositis, immaturity, nonseptic bruises and injuries, and sarcosporidiosis. This provision also applies to unborn calves and to products such as paunches and udders when they have not been handled as required under this subchapter for products for human food purposes; provided, such articles have not been condemned for other pathological reasons. Such permission will be granted only if all parts to be so used will be promptly handled, freely slashed and adequately

identified as required by §325.13(a)(2) of this subchapter. The slashing, identification and packing of the product shall be accomplished in an inedible product area under the supervision of an inspector. Facilities must be adequate so that the carcasses or parts saved under these provisions are not contaminated with pus, manure, septic, or toxic materials, or similar substances. The operation must not result in unsanitary conditions within the establishment.

[35 FR 15575, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 36 FR 11903, June 23, 1971]

PART 315—RENDERING OR OTHER DISPOSAL OF CARCASSES AND PARTS PASSED FOR COOKING

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§315.1 Carcasses and parts passed for cooking; rendering into lard or tallow.

Carcasses and parts passed for cooking may be rendered into lard in accordance with §319.702 of this subchapter or rendered into tallow, provided such rendering is done in the following manner:

(a) When closed rendering equipment is used, the lower opening, except when permanently connected with a blowline, shall first be sealed securely by a Program employee; then the carcasses or parts shall be placed in such equipment in his presence, after which the upper opening shall be securely sealed by such employee. When the product passed for cooking in the tank does not consist of a carcass or whole primal part, the requirements for sealing shall be at the discretion of the circuit supervisor. Such carcasses and parts shall be cooked for a time sufficient to render them effectually into lard or tallow, provided all parts of the products are heated to a temperature not lower than 170 °F. for a period of not less than 30 minutes.

(b) At establishments not equipped with closed rendering equipment for rendering carcasses and parts passed for cooking into lard and tallow, such carcasses or parts may be rendered in open kettles under the direct supervision of a Program employee. Such rendering shall be done during regular hours of work and in compliance with the requirements as to temperature and time specified in paragraph (a) of this section.

[35 FR 15577, Oct. 3, 1970, as amended at 43 FR 25420, June 13, 1978]

§315.2 Carcasses and parts passed for cooking; utilization for food purposes after cooking.

Carcasses and parts passed for cooking may be used for the preparation of meat food products, provided all such carcasses or parts are heated to a temperature not lower than 170 °F. for a period of not less than 30 minutes either before being used in or during the preparation of the finished product.

[37 FR 2661, Feb. 4, 1972]

§315.3 Disposal of products passed for cooking if not handled according to this part.

Products passed for cooking if not handled and processed in accordance with the provisions of this part, shall be disposed of in accordance with §314.1 or §314.3 of this subchapter.

[35 FR 15577, Oct. 3, 1970. Redesignated at 37 FR 2661, Feb. 4, 1972]

PART 316—MARKING PRODUCTS AND THEIR CONTAINERS

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15577, Oct. 3, 1970, unless otherwise noted.

§ 316.1 Authorization required to make devices bearing official marks.

No brand manufacturer, printer or other person shall cast, print, lithograph, or otherwise make or cause to be made any device containing any official mark or simulation thereof without prior written authority therefor from the Administrator as provided for in part 317 of this subchapter.

§ 316.2 Approval required for official marks.

No device containing any official mark shall be made or caused to be made for use on any product until it has been approved by the Administrator as provided for in part 317 of this subchapter.

§ 316.3 Use of official marks prohibited except under supervision of Program employee; removal of official marks, when required.

(a) No person shall affix or place, or cause to be affixed or placed, the official inspection legend or any other official mark, or any abbreviation or simulation of any official mark, to or on any product, or container thereof, except under the supervision of a Program employee, or as authorized by part 317 of this subchapter in connection with the manufacture of containers.

(b) No person shall fill, or cause to be filled, in whole or in part, with any product, any container bearing or intended to bear any official mark, or any abbreviation or simulation of any official mark, except under the supervision of a Program employee.

(c) Product bearing any official mark shall not be canned, cooked, cured, smoked, salted, packed, rendered, or otherwise prepared by any person for commercial purposes unless:

(1) Such preparation is performed at an official establishment; or

(2) Such preparation is conducted under State or other governmental inspection and the prepared product is marked to show that fact; or

(3) The official marks are removed, defaced, or otherwise destroyed before or during such preparation; or

(4) The preparation of the product consists solely of cutting up operations at any establishment exempted from inspection under paragraph 301(c)(2) of the Act or equal provisions of a law of a State or organized Territory or at any establishment in an unorganized Territory exempted under paragraph 23(b) of the Act.

§ 316.4 Marking devices; to be furnished by official establishments; control of.

(a) The operator of each official establishment or official import inspection establishment shall furnish such ink brands, burning brands, and any other device for marking products with official marks as the Administrator may determine is necessary for marking products at such establishment. The official inspection legend on such a device shall be as prescribed in part 312 of this subchapter.

(b) All official devices for marking products with the official inspection legend, or other official inspection marks, including self-locking seals, shall be used only under supervision of a Program employee, and, when not in use for marking shall be kept locked in properly equipped locks or compartments, the keys of which shall not leave the possession of a Program employee, or the locker or compartment shall be sealed with an official seal of

the Department as prescribed in part 312 of this subchapter.

[35 FR 15577, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971; 46 FR 38072, July 24, 1981]

§ 316.5 Branding ink; to be furnished by official establishments; approval by Program; color.

(a) The operator of each official establishment shall furnish all ink for marking products with the official marks at such establishment. Such ink must be made with harmless ingredients that are approved for the purpose by the Administrator. Samples of inks shall be submitted to the Program laboratory from time to time as may be deemed necessary by the inspector in charge.

(b) Only ink approved for the purpose shall be used to apply ink brands bearing official marks to carcasses of cattle, sheep, swine, or goats and fresh meat cuts derived therefrom. Any ink containing F.D. & C. Violet No. 1 shall not be considered an approved ink within the meaning of this paragraph.

(c) Green ink shall not be used to apply marks to carcasses of cattle, sheep, swine, or goats or fresh meat cuts derived therefrom.

(d) Except as provided in paragraphs (b) and (c) of this section, branding ink of any color, approved for the purpose by the Administrator in specific cases, may be used to apply ink brands, bearing official marks, to processed meat cuts derived from cattle, sheep, swine, or goats.

(e) Only green ink approved for the purpose shall be used to apply ink brands bearing official marks to carcasses and parts of carcasses and meat cuts derived from horses, mules, and other equines.

(f) Ink used must assure legibility and permanence of the markings and the color of ink shall provide acceptable contrast with the color of the product to which it is applied.

[35 FR 15577, Oct. 3, 1970, as amended at 38 FR 9088, Apr. 10, 1973]

§ 316.6 Products not to be removed from official establishments unless marked in accordance with the regulations.

No person shall remove or cause to be removed from an official establishment any products which the regulations in this subchapter require to be marked in any way unless they are clearly and legibly marked in compliance with such regulations.

§ 316.7 Marking devices not to be false or misleading; style and size of lettering; approval required.

No brand or other marking device shall be false or misleading. The letters and figures thereon shall be of such style and type as will make a clear and legible impression. All markings to be applied to products in an official establishment shall be approved prior to use by the Administrator as provided for in § 317.3 of this subchapter, except that official markings prescribed by the Federal meat grading regulations (7 CFR 53.19) need not be submitted to the Administrator for approval.

§ 316.8 Unmarked inspected products; moved between official establishments; moved in commerce.

(a) Unmarked products which have been inspected and passed but do not bear the official inspection legend may be transported in compliance with part 325 of this subchapter from one official establishment to another official establishment, for further processing, in a railroad car, truck, or other closed container, if the railroad car, truck, or container is sealed with an official seal of the Department (as prescribed in part 312 of this subchapter) bearing the official inspection legend.

(b) Products which have been inspected and passed but do not bear the official inspection legend may be removed from an official establishment in closed containers bearing the official inspection legend and all other information required by this part and part 317 of this subchapter: *Provided,* That upon removal from such closed container the product may not be further transported in commerce unless such removal is made under the supervision of a Program employee and such product is reinspected by a Program employee and packed under his supervision in containers bearing the official inspection legend and all other information required by this part and part 317 of this subchapter: *And provided further,* That unmarked product shall not

be brought into an official establishment in an open container.

§ 316.9 Products to be marked with official marks.

(a) Each carcass which has been inspected and passed in an official establishment shall be marked at the time of inspection with the official inspection legend containing the number of the official establishment.

(b) Except as provided otherwise in § 316.8, each primal part of a carcass and each liver, beef tongue, and beef heart which has been inspected and passed shall be marked with the official inspection legend containing the number of the official establishment before it leaves the establishment in which it is first inspected and passed, and each such inspected and passed product shall be marked with the official inspection legend containing the number of the official establishment where it was last prepared. Additional official marks of inspection may be applied to products as desired to meet local conditions. Primal parts are the wholesale cuts of carcasses as customarily distributed to retailers. The round, flank, loin, rib, plate, brisket, chuck, and shank are primal parts of beef carcasses. Veal, mutton, and goat primal parts are the leg; flank, loin, rack, breast, and shoulder. The ham, belly, loin, shoulder, and jowl are pork primal parts. Equine primal parts are the round, flank, loin, rib, plate, brisket, chuck, and shank.

(c) Beef livers shall be marked with the official inspection legend containing the number of the official establishment, at which the cattle involved were slaughtered, on the convex surface of the thickest portion of the organ.

(d) Inspected and passed parts of carcasses which are not marked with the official inspection legend under this section shall not enter any official establishment or be sold, transported, or offered for sale or transportation, in commerce, except as provided in § 316.8.

[35 FR 15577, Oct. 3, 1970, as amended at 36 FR 23720, Dec. 14, 1971]

§ 316.10 Marking of meat food products with official inspection legend and ingredient statement.

(a) Inspected and passed sausages and other products in casings or in link form, of the ordinary ''ring'' variety or larger shall be marked with the official inspection legend and list of ingredients in accordance with part 317 of this subchapter. The official marks required by this section shall be branded near each end of the sausage or similar product prepared in casings when the product is of a size larger than that customarily sold at retail intact.

(b) Inspected and passed sausage and other products, in casings or in link form, of the smaller varieties, shall bear one or more official inspection legends and one or more lists of ingredients in accordance with part 317 of this subchapter on each kilogram (2.205 lbs.) of product, except where such products leave the official establishment completely enclosed in properly labeled immediate containers having a capacity of 5 kilograms (11.025 lbs.) or less and containing a single kind of product: *Provided*, That such products in properly labeled closed containers exceeding 5 kilograms (11.025 lbs.) capacity, when shipped to another official establishment for further processing or to a governmental agency, need only have the official inspection legend and list of ingredients shown twice throughout the contents of the container. When such products are shipped to another official establishment for further processing, the inspector in charge at the point of origin shall identify the shipment to the inspector in charge at destination by means of Form MP 408–1.

(c) The list of ingredients may be applied by stamping, printing, using paper bands, tags, or tissue strips, or other means approved by the Administrator in specific cases.

(d) All cured products shall be marked with the list of ingredients in accordance with part 317 of this subchapter.

[35 FR 15577, Oct. 3, 1970, as amended at 37 FR 16863, Aug. 22, 1972; 38 FR 4385, Feb. 14, 1973; 39 FR 36000, Oct. 7, 1974; 44 FR 67088, Nov. 23, 1979]

§ 316.11 Special markings for certain meat food products.

(a) Meat food products prepared in casing or link form (whether or not thereafter subdivided), other than sausage, which possess the characteristics of or resemble sausage, shall bear on each link or piece the word ''imitation'' prominently displayed: *Provided,* That the following need not be so marked if they bear on each link or piece the name of the product in accordance with § 317.2 of this subchapter: Such products as coppa, capocollo, lachschinken, bacon, pork loins, pork shoulder butts, and similar cuts of meat which are prepared without added substance other than curing materials or condiments; meat rolls, bockwurst, and similar products which do not contain cereal or vegetables; headcheese, souse, sulze, scrapple, blood pudding, and liver pudding; and other products such as loaves, chili con carne, and meat and cheese products when prepared with sufficient cheese to give definite characteristics to the finished products: *And provided further,* That imitation sausage packed in properly labeled containers having a capacity of 3 pounds or less and of a kind usually sold at retail intact, need not bear the word ''imitation'' on each link or piece if no other marking or labeling is applied directly to the product.

(b) When cereal, vegetable starch, starchy vegetable flour, soy flour, soy protein concentrate, isolated soy protein, dried milk, nonfat dry milk, or calcium reduced dried skim milk is added to sausage in casing or in link form within the limits prescribed in part 319 of this subchapter, the products shall be marked with the name of each added ingredient, as for example ''cereal added,'' ''potato flour added,'' ''cereal and potato flour added,'' ''soy flour added,'' ''isolated soy protein added,'' ''nonfat dry milk added,'' ''calcium reduced dried skim milk added,'' or ''cereal and nonfat dry milk added,'' as the case may be.

(c)(1) When product is placed in a casing to which artificial coloring is thereafter applied, as permitted in part 318 of this subchapter, the product shall be legibly and conspicuously marked by stamping or printing on the casing the words ''artificially colored.''

(2) If a casing is removed from product at an official establishment and there is evidence of artificial coloring on the surface of the product, the product from which the casing has been removed shall be marked by stamping directly thereon the words ''artificially colored.''

(3) The casing containing product need not be marked to show that it is colored if it is colored prior to its use as a covering for the product, and the coloring is of a kind and so applied as not to be transferable to the product and not to be misleading or deceptive in any respect.

(d) When an approved artificial smoke flavoring or an approved smoke flavoring is added to the formula of any meat food product as permitted in part 318 of this subchapter, the product shall be legibly and conspicuously marked with the words ''Artificial Smoke Flavoring Added'' or ''Smoke Flavoring Added,'' whichever may be applicable.

(e) Subject to the provisions in paragraph (a) of this section, in the case of sausage of the smaller varieties, the markings prescribed in this section may be limited to links bearing the official inspection legend, and such markings shall not be required if the sausages are packed in properly labeled containers having a capacity of 3 pounds or less and of a kind usually sold at retail intact. Further, all markings otherwise required by this section (except those required by paragraph (a) of this section) may be omitted from the casings of sausage and other meat food products when these products are to be processed in sealed metal containers properly labeled in accordance with the requirements in part 317 of this subchapter.

(f) When an approved antioxidant is added to any meat food product as permitted in parts 318 and 319 of this subchapter, the products shall be legibly and conspicuously marked in an approved manner identifying the specific antioxidant used by its common name or approved abbreviation and the purpose for which it is added, such as, ''BHA, BHT, and Propylgallate added to help protect flavor.''

(g) Sausage of the dry varieties treated with potassium sorbate or

propylparaben (propyl p-hydroxybenzoate) as permitted by part 318 of this subchapter shall be marked as prescribed in §317.8(b)(28) of this subchapter).

§ 316.12 Marking of equine carcasses and parts thereof.

(a) All inspected and passed equine carcasses and parts thereof prepared at any establishment shall be conspicuously marked at the time of inspection with the official inspection legend as prescribed in §312.3 of this subchapter and with other information prescribed for marking products in this part.

(b) All equine carcasses and meat and other parts thereof shall be marked to show the kinds of animals from which they were derived, before the products are sold, transported, offered for sale or transportation, or received for transportation in commerce.

§ 316.13 Marking of outside containers.

(a) Except as otherwise provided in part 325 of this subchapter, when any inspected and passed product for domestic commerce is moved from an official establishment, the outside container shall bear an official inspection legend as prescribed in part 312 of this subchapter.

(b) When any product prepared in an official establishment for domestic commerce has been inspected and passed and is enclosed in a cloth or other wrapping, such wrapping shall bear the official inspection legend and official establishment number applied by the approved 2½-inch rubber brand in the form prescribed in part 312 of this subchapter: *Provided*, That the rubber brand may be omitted if the official inspection legend and official establishment number on the product itself are clearly legible through the wrapping or the wrapping is labeled in accordance with part 317 of this subchapter: *Provided further*, That plain unprinted wrappings, such as stockinettes, cheesecloth, paper, and crinkled paper bags, for properly marked products, which are used solely to protect the product against soiling or excessive drying during transportation or storage, need not bear the official inspection legend.

(c) The outside containers of products for export shall be marked in compliance with part 322 of this subchapter as well as this part.

(d) Slack barrels used as outside containers of products shall have a cloth or paper top covering bearing the official inspection legend containing the official establishment number. At the time of removal of the covering, the official inspection legend shall be destroyed.

(e) The outside containers of any product which has been inspected and passed for cooking, pork which has been refrigerated as provided in §318.10(c) of this subchapter, and beef which has been inspected and passed for refrigeration shall bear the markings and tag prescribed in §325.7(b) of this subchapter.

(f) The outside containers of glands and organs which are not used for human food purposes, such as those described in §325.19 of this subchapter, shall be plainly marked with the phrase ''For pharmaceutical purposes,'' ''For organotherapeutic purposes'' or ''For technical purposes,'' as appropriate, with no reference to inspection, and need not bear other markings otherwise required under the regulations in this subchapter.

(g) Stencils, box dies, labels, and brands may be used on shipping containers of properly labeled products and on such immediate containers, of properly marked products, as tierces, barrels, drums, boxes, crates, and large-size fiber-board containers, without approval as provided for in §317.3 of this subchapter: *Provided*, That the stencils, box dies, labels, and brands are not false or misleading and are approved by the inspector in charge. The official inspection legend for use with such markings shall be approved by the Administrator as provided for in part 317 of this subchapter.

(h) The outside containers of livers prepared as described in §314.10(b), shall be marked as prescribed in §314.10(c) of this subchapter.

(i) The outside containers of any equine product shall be marked to show the kinds of animals from which derived, when the products are sold,

transported, offered for sale or transported, or received for transportation in commerce.

[35 FR 15577, Oct. 3, 1970, as amended at 43 FR 29268, July 7, 1978]

§ 316.14 Marking tank cars and tank trucks used in transportation of edible products.

Each tank car and each tank truck carrying inspected and passed product from an official establishment shall bear a label containing the name of the product in accordance with § 317.2 of this subchapter, the official inspection legend containing the number of the official establishment and the words ''date of loading,'' followed by a suitable space in which the date the tank car or tank truck is loaded shall be inserted. The label shall be located conspicuously and shall be printed on material of such character and so affixed as to preclude detachment or effacement upon exposure to the weather. Before the car or truck is removed from the place where it is unloaded, the carrier shall remove or obliterate such label.

[53 FR 28634, July 29, 1988]

§ 316.15 Marking outside containers of inedible grease, etc.

(a) Outside containers of inedible grease, inedible tallow, or other inedible animal fat, or mixture of any such articles, resulting from operations at any official establishment shall be marked conspicuously with the word ''inedible'' prior to removal from the point of filling. Containers, such as tierces, barrels, and half barrels shall have both ends painted white with durable paint, if necessary, to provide a contrasting background, and the word ''inedible'' shall be marked thereon in letters not less than 2 inches high, while on tank cars and tank trucks the letters shall be not less than 4 inches high.

(b) Inspected rendered animal fat which is intended not to be used for human food may also be marked ''inedible'' if handled as provided in paragraph (a) of this section and part 314 of this subchapter.

§ 316.16 Custom prepared products to be marked "Not for Sale."

Carcasses and parts therefrom that are prepared on a custom basis under § 303.1(a)(2) of this subchapter shall be marked at the time of preparation with the term ''Not for Sale'' in letters at least three-eighths inch in height, except that such products need not be so marked if in immediate containers properly labeled in accordance with the regulations in § 317.16 of this subchapter. Ink used for marking such products must comply with the requirements of § 316.5.

[35 FR 15577, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973]

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

Subpart A—General

Sec.

Subpart B—Nutrition Labeling

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15580, Oct. 3, 1970, unless otherwise noted.

Subpart A—General

§317.1 Labels required; supervision by Program employee.

(a) When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in §317.2 except that the following do not have to bear such a label.

(1) Wrappings of dressed carcasses and primal parts in an unprocessed state, bearing the official inspection legend, if such wrappings are intended solely to protect the product against soiling or excessive drying during transportation or storage, and the wrappings bear no information except company brand names, trade marks, or code numbers which do not include any information required by §317.2;

(2) Uncolored transparent coverings, such as cellophane, which bear no written, printed, or graphic matter and which enclose any unpackaged or packaged product bearing all markings required by part 316 of this subchapter which are clearly legible through such coverings;

(3) Animal and transparent artificial casings bearing only the markings required by part 316 of this subchapter;

(4) Stockinettes used as ''operative devices'', such as those applied to cured meats in preparation for smoking, whether or not such stockinettes are removed following completion of the operations for which they were applied;

(5) Containers such as boil-in bags, trays of frozen dinners, and pie pans which bear no information except company brand names, trademarks, code numbers, directions for preparation and serving suggestions, and which are enclosed in a consumer size container that bears a label as described in §317.2;

(6) Containers of products passed for cooking or refrigeration and moved from an official establishment under §311.1 of this subchapter.

(b) Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear all features required on a label for an immediate container.

(c) No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee.

§ 317.2 Labels: definition; required features.

(a) A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.

(b) Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. In order to meet this requirement, such information must appear on the principal display panel except as otherwise permitted in this part. Except as provided in §317.7, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however*, That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(c) Labels of all products shall show the following information on the principal display panel (except as otherwise permitted in this part), in accordance with the requirements of this part or, if applicable, part 319 of this subchapter:

(1) The name of the product, which in the case of a product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in part 319 of this subchapter, shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation, as prescribed in paragraph (e) of this section;

(2) If the product is fabricated from two or more ingredients, the word ''ingredients'' followed by a list of the ingredients as prescribed in paragraph (f) of this section;

(3) The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section;

(4) An accurate statement of the net quantity of contents, as prescribed in paragraph (h) of this section;

(5) An official inspection legend and, except as otherwise provided in paragraph (i) of this section, the number of the official establishment, in the form required by part 312 of this subchapter;

(6) Any other information required by the regulations in this part or part 319 of this subchapter.

(d) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part and part 319 of this subchapter with clarity and conspicuousness and without obscuring of such information by designs or vignettes or crowding. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. The principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is at least the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area that is 40 percent of the product of the height of the container times the circumference of the container, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: *Provided, however*, That if there is immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and

which is reserved for information prescribed in paragraphs (c) (2), (3), and (5), such panel shall be known as the ''20 percent panel'' and such information may be shown on that panel in lieu of showing it on the principal display panel.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

(e)(1) Any descriptive designation used as a product name for a product which has no common or usual name shall clearly and completely identify the product. Product which has been prepared by salting, smoking, drying, cooking, chopping, or otherwise shall be so described on the label unless the name of the product implies, or the manner of packaging shows that the product was subjected to such preparation. The unqualified terms ''meat,'' ''meat byproduct,'' ''meat food product,'' and terms common to the meat industry but not common to consumers such as ''picnic,'' ''butt,'' ''cala,'' ''square,'' ''loaf,'' ''spread,'' ''delight,'' ''roll,'' ''plate,'' ''luncheon,'' and ''daisy'' shall not be used as names of a product unless accompanied with terms descriptive of the product or with a list of ingredients, as deemed necessary in any specific case by the Administrator in order to assure that the label will not be false or misleading.

(2) The product name for a raw meat product that contains added solution and does not meet a standard of identity in 9 CFR part 319 must contain a descriptive designation that includes:

(i) The percentage of added solution (total weight of the solution ingredients divided by the weight of the raw meat without solution or any other added ingredients multiplied by 100). The percentage of added solution must appear as a number (such as, 15, 20, 30) and the percent symbol (%). The percentage of added solution may be declared by the words ''containing'' or ''contains'' (such as, ''contains 15% added solution of water and salt,'' or ''containing 15% added solution of water and teriyaki sauce'').

(ii) The common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight.

(iii) When the descriptive designation includes all ingredients in the solution, a separate ingredients statement is not required on the label. When the descriptive designation includes multi-ingredient components and the ingredients of the component are not declared in the descriptive designation, all ingredients in the product must be declared in a separate ingredients statement on the label as required in §317.2(c)(2) and (f).

(iv) The product name and the descriptive designation must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (⅓) the size of the largest letter.

(v) The word ''enhanced'' cannot be used in the product name.

(3) *Product name and required validated cooking instructions for needle- or blade-tenderized beef products.*

(i) Unless the product is destined to be fully cooked or to receive another full lethality treatment at an official establishment, the product name for a raw or partially cooked beef product that has been mechanically tenderized, whether by needle or by blade, must contain the term ''mechanically tenderized,'' ''needle tenderized,'' or ''blade tenderized,'' as a descriptive designation and an accurate description of the beef component.

(ii) The product name must appear in a single easy-to-read type style and color and on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than ⅓ the size of the largest letter.

(iii) The labels on raw or partially cooked needle- or blade-tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions must contain validated cooking instructions, including the cooking method, that inform consumers that these products need to be cooked to a specified minimum internal temperature, whether the product needs to be held for a specified time at that temperature or higher before consumption to ensure that potential pathogens are destroyed throughout

the product, and a statement that the internal temperature should be measured by a thermometer. These validated cooking instructions may appear anywhere on the label.

(f)(1) The list of ingredients shall show the common or usual names of the ingredients arranged in the descending order of predominance, except as otherwise provided in this paragraph.

(i) The terms spice, natural flavor, natural flavoring, flavor and flavoring may be used in the following manner:

(A) The term ''spice'' means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(B) The term ''natural flavor,'' ''natural flavoring,'' ''flavor'' or ''flavoring'' means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powered onion, powdered garlic, and powdered celery.

(ii) The term ''corn syrup'' may be used to designate either corn syrup or corn syrup solids.

(iii) The term ''animal and vegetable fats'' or ''vegetable and animal fats'' may be used to designate the ingredients of mixtures of such edible fats in product designated ''compound'' or ''shortening.'' ''Animal fats'' as used herein means fat derived from inspected and passed cattle, sheep, swine, or goats.

(iv) When a product is coated with pork fat, gelatin, or other approved substance and a specific declaration of such coating appears contiguous to the name of the product, the ingredient statement need not make reference to the ingredients of such coating.

(v) When two meat ingredients comprise at least 70 percent of the meat and meat byproduct ingredients of a formula and when neither of the two meat ingredients is less than 30 percent by weight of the total meat and meat byproducts used, such meat ingredients may be interchanged in the formula without a change being made in the ingredients statement on labeling materials: *Provided*, That the word ''and'' in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(vi)(A) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided*, That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as ''Contains _____ percent of _____ ,'' ''Less than _____percent of _____ .'' The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(B) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with part 319 of this subchapter and with § 424.21 of subchapter E, and does not exceed the amount shown in the

quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(2) On containers of frozen dinners, entrees, pizzas, and similar consumer packaged products in cartons the ingredient statement may be placed on the front riser panel: *Provided*, That the words ''see ingredients'' followed immediately by an arrow is placed on the principal display panel immediately above the location of such statement without intervening print or designs.

(3) The ingredient statement may be placed on the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container.

(4) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(g)(1) The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as ''Prepared for * * *''. The place of business of the manufacturer, packer, or distributor shall be shown on the label by city, State, and postal ZIP code when such business is listed in a telephone or city directory, and if not listed in such directory, then the place of business shall be shown by street address, city, State, and postal ZIP code.

(2) The name and place of business of the manufacturer, packer, or distributor may be shown:

(i) On the principal display panel, or

(ii) On the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container, or

(iii) On the front riser panel of frozen food cartons, or

(iv) On the information panel.

(h)(1) The statement of net quantity of contents shall appear on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph.

(2) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in §317.19. The statement shall not include any term qualifying a unit of weight, measure, or count such as ''jumbo quart,'' ''full gallon,'' ''giant quart,'' ''when packed,'' ''minimum,'' or words of similar importance.

(3) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel in lines generally parallel to the base: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph (h). In any case, the statement may appear in more than one line. The terms ''net weight'' or ''net wt.'' shall be used when stating the net quantity of contents in terms of weight, and the term ''net contents'' or ''content'' when stating the net quantity of contents in terms of fluid measure.

(4) Except as provided in §317.7, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semisolid viscous or a mixture of solid and liquid. For example, a declaration of ¾-pound avoirdupois weight shall be expressed as ''Net Wt. 12 oz.'' except as provided for in paragraph (h)(5) of this section for random weight packages; a declaration of 1½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz. (1 lb. 8 oz.),'' ''Net Wt. 24 oz. (1½ lb.),'' or ''Net Wt. 24 oz. (1.5 lbs.).''

(5) On packages containing 1 pound or 1 pint and less than 4 pounds or 1

gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parentheses) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart, except that on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. Paragraph (h)(9) of this section permits certain exceptions from the provisions of this paragraph for margarine packages, random weight consumer size packages, and packages of less than ½ ounce net weight. Pargraph (h)(12) of this section permits certain exceptions from the provision of this paragraph for multi-unit packages.

(6) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel of the package and shall be uniform of all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on packages, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on packages, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenths inch in height on packages, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on packages, the principal display panel of which has an area of more than 100 but not more than 400 square inches.

(v) Not less than one-half inch in height on packages, the principal display panel of which has an area of more than 400 square inches.

(7) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). Heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter ''o'' or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(8) The statement shall appear as a distinct item on the principal display panel and shall be separated by a space at least equal to the height of the lettering used in the statement from other printed label information appearing above or below the statement and by a space at least equal to twice the width of the letter ''N'' of the style of type used in the quantity of contents statement from other printed label information appearing to the left or right of the statement. It shall not include any term qualifying a unit of weight, measure, or count such as, ''jumbo quart,'' ''full gallon,'' ''giant quart,'' ''when packed,'' ''Minimum'' or words of similar import.

(9) The following exemptions from the requirements contained in this paragraph (h) are hereby established:

(i) Individually wrapped, random weight consumer size packages shipped in bulk containers (as specified in paragraph (h)(11) of this section) and meat products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined under §317.19 need not bear a net weight statement when shipped from an official establishment, provided that a net weight shipping statement which meets the requirements of paragraph (h)(2) of this section is applied to their shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement on random weight consumer size

packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (h)(2) of this section;

(iii) Individually wrapped and labeled packages of less than ½ ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(iv) Margarine in 1 pound rectangular packages (except packages containing whipped or soft margarine or packages that contain more than four sticks) is exempt from the requirements of paragraphs (h) (3) and (5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel and that the statement be expressed both in ounces and in pounds, if the statement appears as ''1 pound'' or ''one pound'' in a conspicuous manner on the principal display panel.

(v) Sliced shingle packed bacon in rectangular packages is exempt from the requirements of paragraphs (h)(3) and (h)(5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel, and that the statement be expressed both in ounces and in pounds, if the statement appears in a conspicuous manner on the principal display panel.

(10) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(11) As used in this section, a ''random weight consumer size package'' is one which is one of a lot, shipment or delivery of packages of the same product with varying weights and with no fixed weight pattern.

(12) On a multiunit retail package, a statement of the net quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and in parentheses, the total net quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (h)(5) of this section. For the purposes of this section, ''multiunit retail package'' means a package containing two or more individually packaged units of the identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (h) (2), (3), (6), and (8) of this section.

(i) The official establishment number of the official establishment in which the product was processed under inspection shall be placed as follows:

(1) Within the official inspection legend in the form required by part 312 of this subchapter; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix ''EST''; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling material in the

container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as ''EST. No. on Metal Clip'' or ''Est. No. on Pan'', if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix ''EST''.

(j) Labels of any product within any of the following paragraphs shall show the information required by such paragraph for such product:

(1) A label for product which is an imitation of another food shall bear the word ''imitation'' immediately preceding the name of the food imitated and in the same size and style of lettering as in that name and immediately thereafter the word ''ingredients:'' and the names of the ingredients arranged in the order of their predominance.

(2) If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR part 125) established pursuant to sections 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

(3) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of a meat food product, as permitted in part 318 of this subchapter, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as ''Artificial Smoke Flavoring Added'' or ''Smoke Flavoring Added,'' as may be applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring so added as an ingredient in the formula of the meat food product.

(4) When any other artificial flavoring is permitted under part 318 of this subchapter to be added to a product, the ingredient statement shall identify it as ''Artificial Flavoring.''

(5) When artificial coloring is added to edible fats as permitted under part 318 of this subchapter such substance shall be declared on the label in a prominent manner and contiguous to the name of the product by the words ''Artificially colored'' or ''Artificial coloring added'' or ''With added artificial coloring.'' When natural coloring such as annatto is added to edible fats as permitted under part 318 of this subchapter, such substance shall be declared on the label in the same manner by a phrase such as ''Colored with annatto.''

(6) When product is placed in a casing to which artificial coloring is applied as permitted under part 318 of this subchapter, there shall appear on the label, in a prominent manner and contiguous to the name of the product, the words, ''Artificially colored.''

(7) If a casing is removed from product at an official establishment and there is evidence of artificial coloring on the surface of the product, there shall appear on the label, in a prominent manner and contiguous to the name of product, the words ''Artificially colored.''

(8) When a casing is colored prior to its use as a covering for product and the color is not transferred to the product enclosed in the casing, no reference to color need appear on the label but no such casing may be used if it is misleading or deceptive with respect to color, quality, or kind of product, or otherwise.

(9) Product which bears or contains any other artificial coloring, as permitted under part 318 of this subchapter, shall bear a label stating that fact on the immediate container or if there is none, on the product.

(10) When an antioxidant is added to product as permitted under part 318 of this subchapter, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement identifying the officially approved specific antioxidant by its common name or abbreviation thereof and the purpose for which it is added, such as, ''BHA, BHT, and Propylgallate added to help protect flavor.''

(11) Containers of meat packed in borax or other preservative for export to a foreign country which permits the

use of such preservative shall, at the time of packing, be marked ''for export,'' followed on the next line by the words ''packed in preservative,'' or such equivalent statement as may be approved for this purpose by the Administrator and directly beneath this there shall appear the word ''establishment'' or abbreviation thereof, followed by the number of the establishment at which the product is packed. The complete statement shall be applied in a conspicuous location and in letters not less than 1 inch in height.

(12) Containers of other product packed in, bearing, or containing any chemical preservative shall bear a label stating that fact.

(13)(i) On the label of any ''Mechanically Separated (Species)'' described in §319.5(a) of this subchapter, the name of such product shall be followed immediately by the phrase ''for processing'' unless such product has a protein content of not less than 14 percent and a fat content of not more than 30 percent.

(ii) When any ''Mechanically Separated (Species)'' described in §319.5 of this subchapter is used as an ingredient in the preparation of a meat food product and such ''Mechanically Separated (Species)'' contributes 20 mg or more of calcium to a serving of such meat food product, the label of such meat food product shall state the calcium content of such meat food product, determined and expressed as the percentage of the U.S. Recommended Daily Allowance (U.S. RDA) in a serving in accordance with 21 CFR 101.9(b)(1), (c)(7) (i) and (iv), and (e), as part of any nutrition information included on such label, or if such meat food product does not bear nutrition labeling information, as part of a prominent statement in immediate conjunction with the list of ingredients, as follows: ''A _____ serving contains ____% of the U.S. RDA of calcium'', with the blanks to be filled in, respectively, with the quantity of such product that constitutes a serving and the amount of calcium provided by such serving: *Provided*, That, calcium content need not be stated where (*a*) the percent of the U.S. RDA of calcium to be declared would not differ from the percent of the U.S. RDA that would be declared if the meat food product contained only hand deboned ingredients or (*b*) the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more if the meat food product contained only hand deboned ingredients.

(k) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: ''Keep Refrigerated,'' ''Keep Frozen,'' ''Perishable Keep Under Refrigeration,'' or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution and thawed prior to or during display for sale at retail shall bear the statement on the shipping container: ''Keep Frozen.'' The consumer-size containers for such products shall bear the statement ''Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.'' For all perishable canned products the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be in upper case letters at least one-half inch in height.

(l) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, other equine that do not meet the requirements contained in §318.17, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations For Fully-Cooked Patties in §318.23, except as exempted under paragraph (l)(4) of this section.

(1)(i) Safe handling instructions shall accompany every meat or meat product, specified in this paragraph (l) destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared

with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading ''Safe Handling Instructions'' which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (l)(2) and (l)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) The labels of the meat and meat products specified in this paragraph (l) shall include the following rationale statement as part of the safe handling instructions, ''This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Meat and meat products, specified in this paragraph (l), shall bear the labeling statements:

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions, may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Meat or meat products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (l)(1) through (l)(3) of this section.

(m)(1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

[35 FR 15580, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 317.2, see the List of CFR

Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 317.3 Approval of abbreviations of marks of inspection; preparation of marking devices bearing inspection legend without advance approval prohibited; exception.

(a) The Administrator may approve and authorize the use of abbreviations of marks of inspection under the regulations in this subchapter. Such abbreviations shall have the same force and effect as the respective marks for which they are authorized abbreviations.

(b) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label, or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph apply only to labels, or other marking devices, bearing or containing an official inspection legend shown in § 312.2(b), § 312.3(a) (only the legend appropriate for horse meat food products) or § 312.3(b) (only the legend appropriate for other (nonhorse) equine meat food products), or any abbreviations, copy or representation thereof.

(c) No brand manufacturer or other person shall cast or otherwise make, without an official certificate issued in quadruplicate by a Program employee, a brand or other marking device containing an official inspection legend, or simulation thereof, shown in § 312.2(a), § 312.3(a) (only the legend appropriate for horse carcasses and parts of horse carcasses), § 312.3(b) (only the legend appropriate for other equine (nonhorse) carcasses and parts of other (nonhorse) equine carcasses) or § 312.7(a).

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the brand or other marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the brands or other marking devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the brand or other marking device manufacturer.

(3) The manufacturer of the brands or other marking devices shall engrave or otherwise mark each brand or other marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each brand or other marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the brands or other marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such brands or other marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such brand or other marking device which does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such brand or other marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0015)

[35 FR 15580, Oct. 3, 1970, as amended at 50 FR 21422, May 24, 1985]

§§ 317.4–317.5 [Reserved]

§ 317.6 Approved labels to be used only on products to which they are applicable.

Labels shall be used only on products for which they are approved, and only if they have been approved for such

products in accordance with § 317.3: *Provided*, That existing stocks of labels approved prior to the effective date of this section and the quantity of which has been identified to the circuit supervisor as being in storage on said date at the official establishment or other identified warehouse for the account of the operator of the official establishment may be used until such stocks are exhausted, but not later than 1 year after the effective date of this section unless such labels conform to all the requirements of this part and part 319 of this subchapter. The Administrator may upon the show of good cause grant individual extension of time as he deems necessary.

§ 317.7 Products for foreign commerce; printing labels in foreign language permissible; other deviations.

Labels to be affixed to packages of products for foreign commerce may be printed in a foreign language and may show the statement of the quantity of contents in accordance with the usage of the country to which exported and other deviations from the form of labeling required under this part may be approved for such product by the Administrator in specific cases: *Provided*,

(a) That the proposed labeling accords to the specifications of the foreign purchaser,

(b) That it is not in conflict with the laws of the country to which the product is intended for export, and

(c) That the outside container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of this subchapter apply. The inspection legend and the establishment number shall in all cases appear in English but in addition, may appear literally translated in a foreign language.

§ 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

(a) No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading.

(b) The labels and containers of product shall comply with the following provisions, as applicable:

(1) Terms having geographical significance with reference to a locality other than that in which the product is prepared may appear on the label only when qualified by the word ''style,'' ''type,'' or ''brand,'' as the case may be, in the same size and style of lettering as in the geographical term, and accompanied with a prominent qualifying statement identifying the country, State, Territory, or locality in which the product is prepared, using terms appropriate to effect the qualification. When the word ''style'' or ''type'' is used, there must be a recognized style or type of product identified with and peculiar to the area represented by the geographical term and the product must possess the characteristics of such style or type, and the word ''brand'' shall not be used in such a way as to be false or misleading: *Provided*, That a geographical term which has come into general usage as a trade name and which has been approved by the Administrator as being a generic term may be used without the qualifications provided for in this paragraph. The terms ''frankfurter,'' ''vienna,'' ''bologna,'' ''lebanon bologna,'' ''braunschweiger,'' ''thuringer,'' ''genoa,'' ''leona,'' ''berliner,'' ''holstein,'' ''goteborg,'' ''milan,'' ''polish,'' ''italian,'' and their modifications, as applied to sausages, the terms ''brunswick'' and ''irish'' as applied to stews and the term ''boston'' as applied to pork shoulder butts need not be accompanied with the word ''style,'' ''type,'' or ''brand,'' or a statement identifying the locality in which the product is prepared.

(2) Such terms as ''farm'' or ''country'' shall not be used on labels in connection with products unless such products are actually prepared on the farm or in the country: *Provided*, That if the product is prepared in the same way as on the farm or in the country

these terms, if qualified by the word ''style'' in the same size and style of lettering, may be used: *Provided further*, That the term ''farm'' may be used as part of a brand designation when qualified by the word ''brand'' in the same size and style of lettering, and followed with a statement identifying the locality in which the product is prepared: *And Provided further*, That the provisions of this paragraph shall not apply to products prepared in accordance with § 319.106 of this subchapter. Sausage containing cereal shall not be labeled ''farm style'' or ''country style,'' and lard not rendered in an open kettle shall not be designated as ''farm style'' or ''country style.''

(3) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not relieve any establishment from the requirement that its label shall not be misleading in any particular.

(4) The term ''spring lamb'' or ''genuine spring lamb'' is applicable only to carcasses of new-crop lambs slaughtered during the period beginning in March and terminating not beyond the close of the week containing the first Monday in October.

(5)(i) Coverings shall not be of such color, design, or kind as to be misleading with respect to color, quality, or kind of product to which they are applied. For example, transparent or semitransparent coverings for such articles as sliced bacon or fresh (uncooked) meat and meat food products shall not bear lines or other designs of red or other color which give a false impression of leanness of the product. Transparent or semitransparent wrappers, casings, or coverings for use in packaging cured, cured and smoked, or cured and cooked sausage products, and sliced ready-to-eat meat food products may be color tinted or bear red designs on 50 percent of such wrapper or covering: *Provided*, That the transparent or semitransparent portion of the principal display panel is free of color tinting and red designs: *And provided further*, That the principal display panel provides at least 20 percent unobstructed clear space, consolidated in one area so that the true nature and color of the product is visible to the consumer.

(ii) Packages for sliced bacon that have a transparent opening shall be designed to expose, for viewing, the cut surface of a representative slice. Packages for sliced bacon which meet the following specifications will be accepted as meeting the requirements of this subparagraph provided the enclosed bacon is positioned so that the cut surface of the representative slice can be visually examined:

(*a*) For shingle-packed sliced bacon, the transparent window shall be designed to reveal at least 70 percent of the length (longest dimension) of the representative slice, and this window shall be at least 1½ inches wide. The transparent window shall be located not more than five-eighths inch from the top or bottom edge of a 1-pound or smaller package and not more than three-fourths inch from either the top or bottom edge of a package larger than 1 pound.

(*b*) For stack-packed sliced bacon, the transparent window shall be designed to reveal at least 70 percent of the length (longest dimension) of the representative slice and be at least 1½ inches wide.

(6) The word ''fresh'' shall not be used on labels to designate product which contains any sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or which has been salted for preservation.

(7)(i) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be. An ingredient that is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as ''spice and coloring'', or ''flavoring and coloring'', as the case may be, unless such ingredient is designated by its common or usual name.

(ii) Any ingredient not designated in § 317.2(f)(1)(i) of this part whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock and poultry origin must be designated by names that include the species and livestock and

poultry tissues from which the ingredients are derived.

(8) As used on labels of product, the term ''gelatin'' shall mean (i) the jelly prepared in official establishments by cooking pork skins, tendons, or connective tissue from inspected and passed product, and (ii) dry commercial gelatin or the jelly resulting from its use.

(9) Product (other than canned product) labeled with the term ''loaf'' as part of its name:

(i) If distributed from the official establishment in consumer size containers may be in any shape;

(ii) If distributed in a container of a size larger than that sold intact at retail the product shall be prepared in rectangular form, or as in paragraph (b)(9)(iii) of this section;

(iii) If labeled as an ''Old Fashioned Loaf'' shall be prepared in a traditional form, such as rectangular with rounded top or circular with flat bottom and rounded top.

(10) The term ''baked'' shall apply only to product which has been cooked by the direct action of dry heat and for a sufficient time to permit the product to assume the characteristics of a baked article, such as the formation of a brown crust on the surface, rendering out of surface fat, and the caramelization of the sugar if applied. Baked loaves shall be heated to a temperature of at least 160 °F. and baked pork cuts shall be heated to an internal temperature of at least 170 °F.

(11) When products such as loaves are browned by dipping in hot edible oil or by a flame, the label shall state such fact, e.g., by the words ''Browned in Hot Cottonseed Oil'' or ''Browned by a Flame,'' as the case may be, appearing as part of the product name.

(12) The term ''meat'' and the names of particular kinds of meat, such as beef, veal, mutton, lamb, and pork, shall not be used in such manner as to be false or misleading.

(13) The word ''ham,'' without any prefix indicating the species of animal from which derived, shall be used in labeling only in connection with the hind legs of swine. Ham shanks as such or ham shank meat as such or the trimmings accruing in the trimming and shaping of hams shall not be labeled ''ham'' or ''ham meat'' without qualification. When used in connection with a chopped product the term ''ham'' or ''ham meat'' shall not include the skin.

(14) The terms ''shankless'' and ''hockless'' shall apply only to hams and pork shoulders from which the shank or hock has been completely removed, thus eliminating the entire tibia and fibula, or radius and ulna, respectively, together with the overlying muscle, skin, and other tissue.

(15) Such terms as ''meat extract'' or ''extract of beef'' without qualification shall not be used on labels in connection with products prepared from organs or other parts of the carcass, other than fresh meat. Extracts prepared from any parts of the carcass other than fresh meat may be properly labeled as extracts with the true name of the parts from which prepared. In the case of extract in fluid form, the word ''fluid'' shall also appear on the label, as, for example, ''fluid extract of beef.''

(16) [Reserved]

(17) When any product is enclosed in a container along with a packing substance such as brine, vinegar, or agar jelly, a declaration of the packing substance shall be printed prominently on the label as part of the name of the product, as for example, ''frankfurts packed in brine,'' ''lamb tongue packed in vinegar,'' or ''beef tongue packed in agar jelly,'' as the case may be. The packing substance shall not be used in such a manner as will result in the container being so filled as to be misleading.

(18) ''Leaf lard'' is lard prepared from fresh leaf fat.

(19) When lard or hardened lard is mixed with rendered pork fat or hardened rendered pork fat, the mixture shall be designated as ''rendered pork fat'' or ''hardened rendered pork fat,'' as the case may be.

(20) Oil, stearin, or stock obtained from beef or mutton fats rendered at a temperature above 170 °F. shall not be designated as ''oleo oil,'' ''oleo stearin,'' or ''oleo stock,'' respectively.

(21) When not more than 20 percent of beef fat, mutton fat, oleo stearin, vegetable stearin, or hardened vegetable fat is mixed with lard or with rendered pork fat, there shall appear on the

label, contiguous to and in the same size and style of lettering as the name of the product, the words ''beef fat added,'' ''mutton fat added,'' ''oleo stearin added,'' ''vegetable stearin added,'' or ''hardened vegetable fat added,'' as the case may be. If more than 20 percent is added, the product name shall refer to the particular animal fat or fats used, such as, ''Lard and Beef Fat.'' The designation ''vegetable fat'' is applicable to vegetable oil, vegetable stearin, or a combination of such oil and stearin, whereas the designations ''vegetable oil'' and ''vegetable stearin'' shall be applicable only to the oil and the stearin respectively, when used in meat food products.

(22) Cooked, cured, or pickled pigs feet, pigs knuckles, and similar products, shall be labeled to show that the bones remain in the product, if such is the case. The designation ''semi-boneless'' shall not be used if less than 50 percent of the total weight of bones has been removed.

(23) When monoglycerides, diglycerides, and/or polyglycerol esters of fatty acids are added to rendered animal fat or a combination of such fat and vegetable fat, there shall appear on the label in a prominent manner and contiguous to the name of the product a statement such as ''With Monoglycerides and Diglycerides Added,'' or ''With Diglycerides and Monoglycerides,'' or ''With Polyglycerol Esters of Fatty Acids'' as the case may be.

(24) Section 407 of the Federal Food, Drug, and Cosmetic Act contains provisions with respect to colored margarine or colored oleomargarine (21 U.S.C. 347) which are set forth herein as footnote. [1]

(25) When approved proteolytic enzymes as permitted in part 318 of this subchapter are used on steaks or other raw meat cuts, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement, ''Tenderized with [approved enzyme],'' to indicate the use of such enzymes. Any other approved substance which may be used in the solution shall also be included in the statement.

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[1] ''Sec. 407(a) Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this Act as if it had been introduced in interstate commerce.

(b) No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) Such oleomargarine or margarine is packaged,

(2) The net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) There appears on the label of the package (A) The word 'oleomargarine' or 'margarine' in type or lettering at least as large as any other type or lettering on such label, and (B) A full and accurate statement of all the ingredients contained in such oleomargarine, or margarine, and

(4) Each part of the contents of the package is contained in a wrapper which bears the word 'oleomargarine' or 'margarine' in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this Act.

(c) No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this Act (except subsection (a) and (f) of section 343 of this title) if it complies with the requirements of subsection (b) of this section.

(e) For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six tenths degrees of yellow or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent'' (21 U.S.C. 347).

When approved inorganic chlorides as permitted in part 318 of this subchapter are used on steaks or other raw meat cuts there shall appear on the label in a prominent manner, contiguous to the product name, the statement, ''Tenderized with (names of approved inorganic chloride(s))'' to indicate the use of such inorganic chlorides. Any other approved substance which may be in the solution shall also be included in the statement.

(26) When dimethylpolysiloxan is added as an antifoaming agent to rendered fats, its presence shall be declared on the label contiguous to the name of the product. Such declaration shall read ''Dimethylpolysiloxan Added.''

(27) When pizzas are formulated with crust containing calcium propionate or sodium propionate, there shall appear on the label contiguous to the name of the product the statement ''_____ added to retard spoilage of crust'' preceded by the name of the preservative.

(28) Sausage of the dry varieties treated with potassium sorbate or propylparaben (propyl p-hydroxybenzoate) as permitted by part 318 of this subchapter, shall be marked or labeled with a statement disclosing such treatment and the purpose thereof, such as ''dipped in a potassium sorbate solution to retard mold growth.''

(29) Meat of goats shall be identified as goat meat or chevon.

(30) The term ''Chitterlings'' shall apply to the large intestines of swine, or young bovine animals when preceded with the word ''Calf'' or ''Veal.'' Meat food products that contain chitterlings or calf or veal chitterlings, in accordance with § 318.6(b)(8) of this subchapter shall be identified with product names that refer to such ingredients, as for instance, ''Chitterling Loaf,'' ''Chitterling Pie,'' or ''Calf Chitterlings and Gravy,'' and shall be packed in containers having a capacity of 3 pounds or less and of a kind usually sold at retail intact and bearing such other information as is required by this part.

(31) Products that contain blood from livestock as permitted by part 318 of this subchapter shall be labeled with a name that includes the term ''blood,'' and the specific kind of blood shall be declared in the ingredient statement, e.g., ''Swine blood,'' in the manner required by this part.

(32) A calendar date may be shown on labeling when declared in accordance with the provisions of this subparagraph:

(i) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(ii) Immediately adjacent to the calendar date there must be a phrase explaining the meaning of the date, in terms of ''packing'' date, ''sell by'' date, or ''use before'' date, with or without a further qualifying phrase, e.g., ''For Maximum Freshness'' or ''For Best Quality.''

(33) [Reserved]

(34) The terms ''All,'' ''Pure,'' ''100%,'' and terms of similar connotation shall not be used on labels for products to identify ingredient content, unless the product is prepared solely from a single ingredient.

(35) When agar-agar is used in canned jellied meat food products, as permitted in part 318 of this subchapter, there shall appear on the label in a prominent manner, contiguous to the product name, a statement to indicate the use of agar-agar.

(36) When sodium alginate, calcium carbonate, and lactic acid and calcium carbonate (or glucono delta-lactone) are used together in a dry binding matrix in restructured, formed meat food products, as permitted in part 318 of this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate and lactic acid and calcium carbonate (or glucono delta-lactone).

(37) The labels of sausages encased in natural casings made from meat or poultry viscera shall identify the type of meat or poultry from which the casings were derived, if the casings are

from a different type of meat or poultry than the encased meat or poultry. The identity of the casing, if required, may be placed on the principal display panel or in the ingredient statement. Establishments producing, manufacturing, or using natural sausage casings are to maintain records documenting the meat or poultry source in accordance with part 320 of this chapter.

(38) The labels of sausages encased in regenerated collagen casings shall disclose this fact on the product label. The fact that the sausage is encased in collagen may be placed on the principal display panel or in the ingredient statement.

(39) When transglutaminase enzyme is used to bind pieces of meat to form a cut of meat, or to reform a piece of meat from a multiple cuts, there shall appear on the label, as part of the product name, a statement that indicates that the product has been ''formed'' or ''reformed,'' in addition to other preparation steps, e.g., ''Formed Beef Tenderloin'' or ''Reformed and Shaped Beef Tenderloin.''

(40) A country of origin statement on the label of any meat ''covered commodity'' as defined in 7 CFR Part 65, Subpart A, that is to be sold by a ''retailer,'' as defined in 7 CFR 65.240, must comply with the requirements in 7 CFR 65.300 and 65.400.

[35 FR 15580, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 317.8, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 317.9 Labeling of equine products.

The immediate containers of any equine products shall be labeled to show the kinds of animals from which derived when the products are sold, transported, offered for sale or transportation or received for transportation in commerce.

§ 317.10 Reuse of official inspection marks; reuse of containers bearing official marks, labels, etc.

(a) No official inspection legend or other official mark which has been previously used shall be used again for the identification of any product, except as provided for in paragraph (b) of this section.

(b) All stencils, marks, labels, or other labeling on previously used containers, whether relating to any product or otherwise, shall be removed or obliterated before such containers are used for any product, unless such labeling correctly indicates the product to be packed therein and such containers are refilled under the supervision of a Program employee.

§ 317.11 Labeling, filling of containers, handling of labeled products to be only in compliance with regulations.

(a) No person shall in any official establishment apply or affix, or cause to be applied or affixed, any label to any product prepared or received in such establishment, or to any container thereof, or fill any container at such an establishment, except in compliance with the regulations in this subchapter.

(b) No covering or other container shall be filled, in whole or in part, at any official establishment with any product unless it has been inspected and passed in compliance with the regulations in this subchapter, is not adulterated, and is strictly in accordance with the statements on the label, and such filling is done under the supervision of a Program employee.

(c) No person shall remove, or cause to be removed from an official establishment any product bearing a label unless such label is in compliance with the regulations in this subchapter, or any product not bearing a label required by such regulations.

§ 317.12 Relabeling products; requirements.

When it is claimed by an official establishment that any of its products which bore labels bearing official marks has been transported to a location other than an official establishment, and it is desired to relabel the product because the labels have become mutilated or otherwise damaged, a request for relabeling the product shall be sent to the Administrator, accompanied with a statement of the reasons therefor. Labeling material intended for relabeling inspected and

passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with labels bearing any official marks shall be done under the supervision of a Program inspector. The official establishment shall reimburse the Program, in accordance with the regulations of the Department, for any cost involved in supervising the relabeling of such product.

§ 317.13 Storage and distribution of labels and containers bearing official marks.

Labels, wrappers, and containers bearing any official marks, with or without the establishment number, may be transported from one official establishment to any other official establishment provided such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subchapter.

§§ 317.14–317.15 [Reserved]

§ 317.16 Labeling and containers of custom prepared products.

Products that are custom prepared under § 303.1(a)(2) of this subchapter must be packaged immediately after preparation and must be labeled (in lieu of information otherwise required by this part 317) with the words ''Not For Sale'' in lettering not less than three-eighth inch in height. Such exempted custom prepared products or their containers may bear additional labeling provided such labeling is not false or misleading.

[37 FR 4071, Feb. 26, 1972]

§ 317.17 Interpretation and statement of labeling policy for cured products; special labeling requirements concerning nitrate and nitrite.

(a) With respect to sections 1(n) (7), (9), and (12) of the Act and § 317.2, any substance mixed with another substance to cure a product must be identified in the ingredients statement on the label of such product. For example, curing mixtures composed of such ingredients as water, salt, sugar, sodium phosphate, sodium nitrate, and sodium nitrite or other permitted substances which are added to any product, must be identified on the label of the product by listing each such ingredient in accordance with the provisions of § 317.2.

(b) Any product, such as bacon and pepperoni, which is required to be labeled by a common or usual name or descriptive name in accordance with § 317.2(c)(1) and to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name when immediately preceded with the term ''Uncured'' as part of the product name in the same size and style of lettering as the product name, provided that the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate or nitrite, or both.

(c)(1) Products described in paragraph (b) of this section or § 319.2 of this subchapter, which contain no nitrate or nitrite shall bear the statement ''No Nitrate or Nitrite Added.'' This statement shall be adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name.

(2) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall bear, adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement ''Not Preserved—Keep Refrigerated Below 40 °F. At All Times'' unless they have been thermally processed to F_o 3 or more; they have been fermented or pickled to pH of 4.6 or less; or they have been dried to a water activity of 0.92 or less.

(3) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall not be subject to the labeling requirements of paragraphs (b) and (c) of this section if they contain an amount of salt sufficient to achieve

a brine concentration of 10 percent or more.

[37 FR 16863, Aug. 22, 1972, as amended at 44 FR 48961, Aug. 21, 1979]

§§ 317.18–317.23 [Reserved]

§ 317.24 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for their intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and any other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will monitor the use of packaging material in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information tm designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request—a minimum of 30 days—any applicable guaranty shall cease to be effective, and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(e) The Administrator may disapprove for use in official establishments packaging materials whose use cannot be confirmed as complying with FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a

hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2235, Jan. 19, 1984. Redesignated at 55 FR 49833, Nov. 30, 1990]

Subpart B—Nutrition Labeling

SOURCE: 58 FR 664, Jan. 6, 1993, unless otherwise noted.

§ 317.300 Nutrition labeling of meat and meat food products.

(a) Nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale, except single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301 and are not major cuts of single-ingredient, raw meat products identified in § 317.344, unless the product is exempted under § 317.400 . Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat products identified in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials, except as exempted under § 317.400. For all other products for which nutrition labeling is required, including ground or chopped meat products described in § 317.301, nutrition labeling must be provided in accordance with the provisions of § 317.309, except as exempted under § 317.400.

(b) Nutrition labeling may be provided for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301 and that are not major cuts of single-ingredient, raw meat products identified in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials.

[75 FR 82164, Dec. 29, 2010]

§ 317.301 Required nutrition labeling of ground or chopped meat products.

(a) Nutrition labels must be provided for all ground or chopped products (livestock species) and hamburger with or without added seasonings (including, but not limited to, ground beef, ground beef patties, ground sirloin, ground pork, and ground lamb) that are intended for human consumption and offered for sale, in accordance with the provisions of § 317.309, except as exempted under § 317.400.

(b) [Reserved]

[75 FR 82165, Dec. 29, 2010]

§ 317.302 Location of nutrition information.

(a) Nutrition information on a label of a packaged meat or meat food product shall appear on the label's principal display panel or on the information panel, except as provided in paragraphs (b) and (c) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

(c) Meat or meat food products in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information may use any alternate panel that can be

readily seen by consumers for the nutrition information. In determining the sufficiency of available space for the nutrition information, the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered.

[58 FR 664, Jan. 6, 1993, as amended at 59 FR 40213, Aug. 8, 1994; 60 FR 176, Jan. 3, 1995]

§§ 317.303–317.307 [Reserved]

§ 317.308 Labeling of meat or meat food products with number of servings.

The label of any package of a meat or meat food product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 317.2(h)(10).

[58 FR 664, Jan. 6, 1993, as amended at 60 FR 176, Jan. 3, 1995]

§ 317.309 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term ''serving'' or ''serving size'' means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the ''Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply'' (Reference Amount(s)) that appear in § 317.312(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, ''for sale only through the _____ program'' (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. However, the Reference Amounts in § 317.312(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product ''as packaged'' for all products, except that single-ingredient, raw products that are not ground or chopped meat products described in § 317.301 may be declared on the basis of the product ''as consumed''. For single-ingredient, raw products that are not ground or chopped meat products described in § 317.301, if data are based on the product 'as consumed,' the data must be presented in accordance with § 317.345(d). In addition to the required declaration on the basis of ''as packaged'' for products other than single-ingredient, raw products that are not ground or chopped meat products described in § 317.301, the declaration may also be made on the basis of ''as consumed,'' provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., hot dogs, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare one unit as the serving size if the whole unit can reasonably be consumed at a single eating occasion.

(v) For products that have Reference Amounts of 100 grams (or milliliter) or larger and are individual units within a multi-serving package, if a unit contains more than 150 percent but less than 200 percent of the Reference Amount, the manufacturer may decide whether to declare the individual unit as 1 or 2 servings.

(vi) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 317.312(c).

(vii) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g. pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g., ⅛ quiche, ¼ pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 317.312(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 317.312(c). In expressing the fractional slice, manufacturers shall use ½, ⅓, ¼, ⅕, ⅙, or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole roast beef, marinated beef tenderloin, large can of chili), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., roast beef and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product determined in § 317.312(c).

(7) For labeling purposes, the term ''common household measure'' or ''common household unit'' means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in ¼- or ⅓-cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 2 tablespoons (tbsp), 1, 1⅓, 1½, or 1 ⅔ tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in ¼-tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece,

slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term ''about'' (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., chop, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., ham with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size may be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 317.312(b) and the procedures described in this section, falls exactly half way between two serving sizes (e.g., 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually and that contains less than 200 percent of the applicable Reference Amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving, except for products that have Reference Amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the Reference Amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable Reference Amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section. However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single-servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced bologna. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following

abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term ''about'' (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size (e.g., pickled pigs feet), the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, a manufacturer may declare ''varied'' for the number of servings per container provided the nutrition information is based on the Reference Amount expressed in ounces. The manufacturer may provide the typical number of servings in parenthesis following the ''varied'' statement (e.g., varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit. The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw meat products that are not ground or chopped meat products described in §317.301, including those that have been previously frozen.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of single-ingredient, raw products that are not ground or chopped meat products described in §317.301 and products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) The serving size for meal-type products and main-dish products as defined in §317.313(l) and §317.313(m) in single-serving containers will be the entire edible content of the package. Serving size for meal-type products and main-dish products in multi-serve containers will be based on the reference amount applicable to the product in §317.312(b) if the product is listed in §317.312(b). Serving size for meal-type products and main-dish products in multi-serve containers that are not listed in §317.312(b) will be based on the reference amount according to §317.312(c), (d), and (e).

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by §317.309(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(14) If a product consists of assortments of meat or meat food products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup

mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided,* That the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(c) The declaration of nutrition information on the label or in labeling of a meat or meat food product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraph (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraph (d) or (e) of this section.

(1) ''Calories, total,'' ''Total calories,'' or ''Calories'': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, page 25, ''Energy Value of Foods—Basis and Derivation,'' by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA), Agriculture Handbook No. 74 (Slightly revised February 1973), which is incorporated by reference. Table 13 of the ''Energy Value of Foods—Basis and Derivation,'' Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference. Pages 9–11, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.); or

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts

172 or 184 of 21 CFR, or by other means, as appropriate.

(ii) ''Calories from fat'': A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of ''calories from fat'' is not required on products that contain less than 0.5 gram of fat per serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section.

(iii) ''Calories from saturated fat'' or ''Calories from saturated'' (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat per serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) ''Saturated fat'' or ''Saturated'': A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat or cholesterol content, and if ''calories from saturated fat'' is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(A) ''Stearic Acid'' (VOLUNTARY): A statement of the number of grams of stearic acid per serving may be declared voluntarily, except that when a claim is made about stearic acid, label declaration shall be required. Stearic acid content shall be indented under saturated fat and expressed to the nearest 0.5 (½)-gram increment below 5 grams and the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(B) [Reserved]

(ii) ''Polyunsaturated fat'' or ''Polyunsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 317.362(b)(1) for a claim for ''fat free,'' label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) ''Monounsaturated fat'' or ''Monounsaturated'' (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 317.362(b)(1) for a claim for ''fat free,'' label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) ''Cholesterol'': A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as ''less than 5 milligrams.''

(4) ''Sodium'': A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) ''Potassium'' (VOLUNTARY): A statement of the number of milligrams of potassium per serving may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(6) ''Carbohydrate, total'' or ''Total carbohydrate'': A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2 and 3, which is incorporated by reference. Pages 2 and 3, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.)

(i) ''Dietary fiber'': A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(A) ''Soluble fiber'' (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) ''Insoluble fiber'' (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) ''Sugars'': A statement of the number of grams of sugars per serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about

sweeteners, sugars, or sugar alcohol content. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) ''Sugar alcohol'' (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term ''sugar alcohol,'' the name of the specific sugar alcohol (e.g., ''xylitol'') present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less then 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) ''Other carbohydrate'' (VOLUNTARY): A statement of the number of grams of other carbohydrate per serving may be declared voluntarily. Other carbohydrate shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) ''Protein'': A statement of the number of grams of protein per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement ''not a significant source of protein,'' or a listing aligned under the column headed ''Percent Daily Value'' of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be for infants, the statement ''not a significant source of protein'' shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 317.309(h), except when the procedure for a specific food requires another factor.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of

the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed ''Percent Daily Value,'' and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be for infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The corrected amount of protein (grams) per serving for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8 in ''Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1990, which is incorporated by reference. Sections 5.4.1, 7.2.1, and 8 of the ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' as published by the Food and Agriculture Organization of the United Nations/World Health Organization, is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700. For products represented or purported to be for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For products represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on products represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be

given to both values in all such labeling. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of _____ (listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units
Vitamin C, 60 milligrams
Calcium, 1.0 gram
Iron, 18 milligrams
Vitamin D, 400 International Units
Vitamin E, 30 International Units
Thiamin, 1.5 milligrams
Riboflavin, 1.7 milligrams
Niacin, 20 milligrams
Vitamin B_6, 2.0 milligrams
Folate, 0.4 milligram
Vitamin B_{12}, 6 micrograms
Biotin, 0.3 milligram
Pantothenic acid, 10 milligrams
Phosphorus, 1.0 gram
Iodine, 150 micrograms
Magnesium, 400 milligrams
Zinc, 15 milligrams
Copper, 2.0 milligrams

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., ''Percent Daily Value: Vitamin A 50 (90 percent as *beta*-carotene)''). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat	grams (g)	65
Saturated fatty acids	do	20
Cholesterol	milligrams (mg)	300
Total carbohydrate	grams (g)	300
Fiber	do	25
Sodium	milligrams (mg)	2,400
Potassium	do	3,500
Protein	grams (g)	50

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, except on products on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on products for infants and children less than 4 years of age as provided for in § 317.400(c), and on products in packages that have a total surface area available to bear labeling of 40 or less square inches as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(3), (d)(5), (d)(7), and (d)(8) of this section shall be in type size no smaller than 8 point. Except for the heading ''Nutrition Facts,'' the information required in paragraphs (d)(4), (d)(6), and (d)(9) of this section and all other information contained within the nutrition label shall be in type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall also be in type no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., ''Nutrition Facts,'' ''Amount per Serving,'' and ''% Daily Value*''), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., Calories, Total fat, Cholesterol, Sodium, Potassium, Total carbohydrate, and Protein), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate ''Amount Per Serving'' from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it.

(2) The information shall be presented under the identifying heading of ''Nutrition Facts'' which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section.

(3) Information on serving size shall immediately follow the heading. Such information shall include:

(i) ''Serving Size'': A statement of the serving size as specified in paragraph (b)(9) of this section.

(ii) ''Servings Per Container'': The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section or on single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301.

(4) A subheading ''Amount Per Serving'' shall be separated from serving size information by a bar.

(5) Information on calories shall immediately follow the heading ''Amount Per Serving'' and shall be declared in one line, leaving sufficient space between the declaration of ''Calories''

and ''Calories from fat'' to allow clear differentiation, or, if ''Calories from saturated fat'' is declared, in a column with total ''Calories'' at the top, followed by ''Calories from fat'' (indented), and ''Calories from saturated fat'' (indented).

(6) The column heading ''% Daily Value,'' followed by an asterisk (e.g., ''% Daily Value*''), shall be separated from information on calories by a bar. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column headings ''Percent Daily Value,'' ''Percent DV,'' or ''% DV'' may be substituted for ''% Daily Value.''

(7) Except as provided for in paragraph (g) of this section, and except as permitted by § 317.400(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams or ''mg'' for milligrams.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading ''% Daily Value'' established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) or may be listed in two columns, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed ''% Daily Value.''

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state: Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total fat	Less than	65 g	80 g
Saturated fat	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2,400 mg	2,400 mg
Total carbohydrate		300 g	375 g
Dietary fiber		25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(7)(ii) of this section, protein shall be listed under dietary fiber, and a value of 50 g shall be inserted on the same line in the column headed ''2,000'' and value of 65 g in the column headed ''2,500.''

(iii) If potassium is declared in the column described in paragraph (d)(7)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (g)(2) of this section may be used within the footnote.

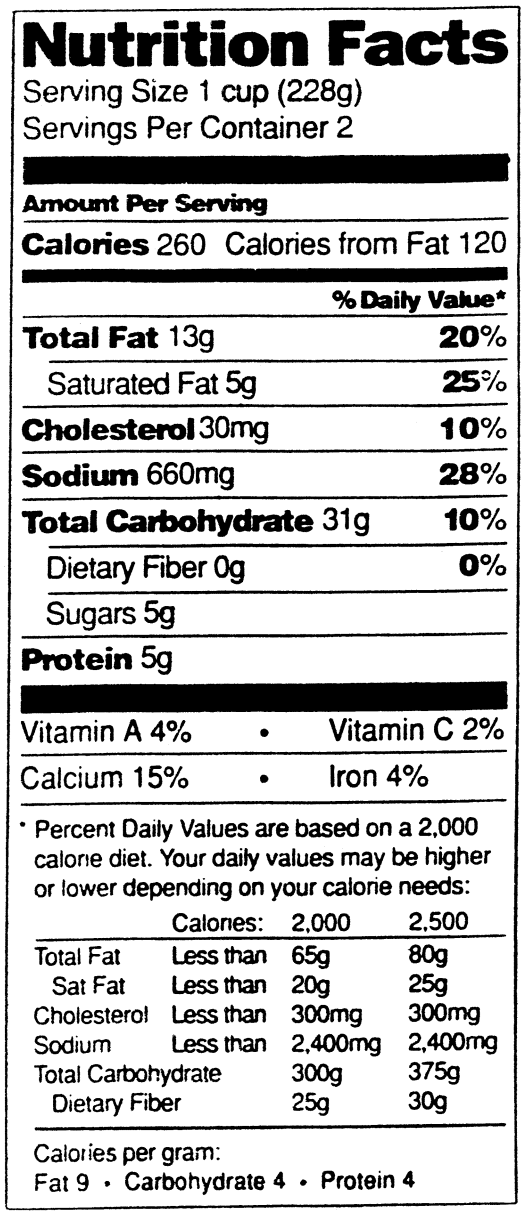
(10) Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (i.e., ''Calories per gram: Fat 9, Carbohydrate 4, Protein 4'') or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of iron is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron, the nutrition label may be presented in a tabular display in which the footnote required by paragraph (d)(9) of the section is given to the far right of the label, and additional vitamins and minerals beyond the four that are required (i.e., vitamin A, vitamin C, calcium, and iron) are arrayed horizontally following declarations of the required vitamins and minerals.

(12) The following sample label illustrates the provisions of paragraph (d) of this section:



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(13)(i) Nutrition labeling on the outer label of packages of meat or meat food products that contain two or more products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type of food (e.g., meat salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph

(d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the ''Nutrition Facts'' title, and both the quantitative amount by weight (i.e., g/mg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., ''Protein/Proteinas 2 g''). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both ''raw'' and ''cooked'') or for common combinations of foods as provided for in paragraph (b) of this section, or for different units (e.g., per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established (e.g., both infants and children less than 4 years of age) as provided for in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of ''Amount Per Serving,'' there shall be two or more column headings accurately describing the forms of the same product (e.g., ''raw'' and ''roasted''), the combinations of foods, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the Reference Amount in § 317.312(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same product, for combinations of foods, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged, but may be on the basis of 'as consumed' for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301, and according to the label serving size based on the Reference Amount in § 317.312(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged, but may be on the basis of 'as consumed' for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301, and according to the label serving size based on the Reference Amount in § 317.312(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

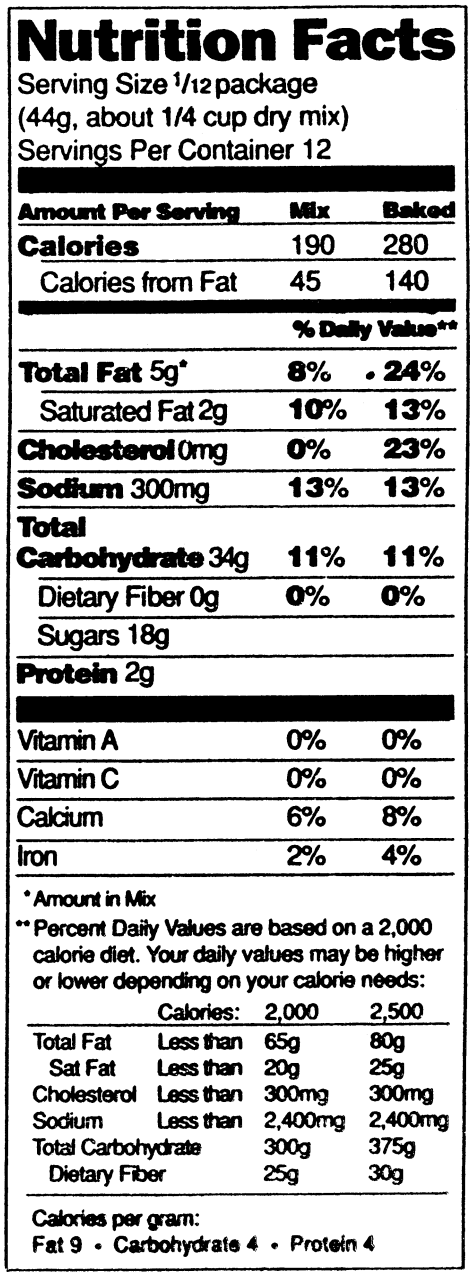
(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged, but may be on the basis of 'as consumed' for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301, for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., ½ cup

skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., ''Total fat (2 g)*'') referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading ''% DAILY VALUE'' and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:



Nutrition Facts

Serving Size 1/12 package
(44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	**8%**	**12%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**13%**	**13%**
Total Carbohydrate 34g	**11%**	**11%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(f)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients

(i.e., calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, sodium, and protein;

(ii) Any of the following that are present in more than insignificant amounts: Calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included at the bottom of the nutrition label, ''Not a significant source of _____.'' The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).''

(5) Except as provided for in paragraph (g) of this section and in § 317.400(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required. When the footnote is omitted, an asterisk shall be placed at the bottom of the label followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the heading, a statement that ''DV'' represents ''Daily Value.''

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 317.302(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(ii) When nutrition information is given in a linear display, the nutrition information shall be set off in a box by the use of a hairline. The percent Daily Value is separated from the quantitative amount declaration by the use of parenthesis, and all nutrients, both principal components and subcomponents, are treated similarly. Bolding is required only on the title ''Nutrition Facts'' and is allowed for nutrient names for ''Calories,'' ''Total fat,'' ''Cholesterol,'' ''Sodium,'' ''Total carbohydrate,'' and ''Protein.''

(2) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from fat—Fat cal
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Other carbohydrate—Other carb

(3) Omitting the footnote required in paragraph (d)(9) of this section and placing another asterisk at the bottom of the label followed by the statement

''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the heading, a statement that ''DV'' represents ''Daily Value.''

(4) Presenting the required nutrition information on any other label panel.

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the ''Chemistry Laboratory Guidebook,'' or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the ''Official Methods of Analysis'' of the AOAC International, formerly Association of Official Analytical Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 317.309(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The ''Official Methods of Analysis'' is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., suite 400, Arlington, VA 22201. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section

1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls above this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h) (1) through (8) of this section shall not apply to single-ingredient, raw meat products that are not ground or chopped meat products described in §317.301, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference as provided in §317.345(e) and (f).

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088)

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993; 58 FR 47627, Sept. 10, 1993; 59 FR 45194, Sept. 1, 1994; 60 FR 176, Jan. 3, 1995; 69 FR 58801, Oct. 1, 2004; 75 FR 82165, Dec. 29, 2010]

§§ 317.310–317.311 [Reserved]

§ 317.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground beef), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1] [2] [3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g
Plain meats and meat sticks, ready-to-serve	55 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1] [2] [3] [4] [5]

Product category	Reference amount	Reference amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young	110 g	n/a.
Lard, margarine, shortening	1 tbsp	n/a.
Salad and potato toppers; e.g., bacon bits	7 g	n/a.
Bacon (bacon, beef breakfast strips, pork breakfast strips, pork rinds)	15 g	54 g = bacon. 30 g = breakfast strips.
Dried; e.g., jerky, dried beef, Parma ham sausage products with a moisture/protein ratio of less than 2:1; e.g., pepperoni.	30 g	n/a.
Snacks; e.g., meat snack food sticks	30 g	n/a.
Luncheon meat, bologna, Canadian style bacon, pork pattie crumbles, beef pattie crumbles, blood pudding, luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelet, Lebanon bologna, potted meat food product, taco fillings, meat pie fillings.	55 g	n/a.
Linked meat sausage products, Vienna sausage, frankfurters, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, smoked or pickled meat, pickled pigs feet.	55 g	n/a. 75 g = uncooked sausage.
Entrees without sauce, cuts of meat including marinated, tenderized, injected cuts of meat, beef patty, corn dog, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g	114 g.
Canned meats, canned beef, canned pork. [4]	55 g	n/a.
Entrees with sauce, barbecued meats in sauce	140 g	n/a.
Mixed dishes NOT measurable with a cup; [5] e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches, cracker and meat lunch type packages, gyro, stromboli, burger on a bun, frank on a bun, calzone, taco, pockets stuffed with meat, foldovers, stuffed vegetables with meat, shish kabobs, empanada.	140 g (plus 55 g for products with sauce toppings)	n/a.
Mixed dishes measurable with a cup; e.g., meat casserole, macaroni and cheese with meat, pot pie, spaghetti with sauce, meat chili, chili with beans, meat hash, creamed chipped beef, beef ravioli in sauce, beef stroganoff, Brunswick stew, goulash, meat stew, ragout, meat lasagna, meat filled pasta.	1 cup	n/a.
Salads—pasta or potato, potato salad with bacon, macaroni and meat salad	140 g	n/a.
Salads—all other meat, salads, ham salad	100 g	n/a.
Soups—all varieties	245 g	n/a.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1] [2] [3] [4] [5]—Continued

Product category	Reference amount	Reference amount
	Ready-to-serve	Ready-to-cook
Major main entree type sauce; e.g., spaghetti sauce with meat, spaghetti sauce with meatballs.	125 g	n/a.
Minor main entree sauce; e.g., pizza sauce with meat, gravy	¼ cup	n/a.
Seasoning mixes dry, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat..		
As reconstituted:		
Amount to make one Reference Amount of the final dish; e.g.,		
Gravy	¼ cup	n/a.
Major main entree type sauce	125 g	n/a.
Soup	245 g	n/a.
Entree measurable with a cup	1 cup	n/a.

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.
[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.
[4] If packed or canned in liquid, the Reference Amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed.
[5] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (e.g., lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) For bulk products, the Reference Amount for the combined product shall be the Reference Amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.

(2) For products where the ingredient represented as the main ingredient is one or more discrete units, the Reference Amount for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the Reference Amount for that ingredient as established in paragraph (b) of this section plus proportioned amounts of all minor ingredients.

(3) If the Reference Amounts are in compatible units, they shall be summed (e.g., ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, the weights of the appropriate volumes should be used (e.g., grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 317.313(d), such as a ''low calorie'' version, shall be the

same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parentheses, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.312 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., ham as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to

the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of meat food products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of an answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the

use of the Reference Amount and/or Product Category.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088)

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 186, Jan. 3, 1995]

§ 317.313 Nutrient content claims; general principles.

(a) This section applies to meat or meat food products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 317.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., ''low sodium'' or ''contains 100 calories.''

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., ''high in oat bran''); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., ''healthy, contains 3 grams (g) of fat'').

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in subpart B of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., ''hi'' or ''lo'').

(c) Information that is required or permitted by § 317.309 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A ''substitute'' product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an ''imitation.''

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., ''not recommended for frying'').

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 317.2(h) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(e)(1) Because the use of a ''free'' or ''low'' claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., ''low sodium beef noodle soup'').

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered,

formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., ''lard, a sodium free food'').

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 317.313, 317.354, 317.356, 317.360, 317.361, 317.362, and 317.380, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 317.400(d)(2).

(h) [Reserved]

(i) Except as provided in § 317.309 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart B of this part, for the nutrient that the label addresses. Such a claim might be, ''less than 10 g of fat per serving;''

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not ''low'' in or a ''good source'' of the nutrient, such as ''only 200 milligrams (mg) sodium per serving, not a low sodium product.'' The disclaimer must be in easily legible print or type and in a size no less than required by § 317.2(h) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., ''100 calories'' or ''5 grams of fat''), in which case no disclaimer is required.

(4) ''Percent fat free'' claims are not authorized by this paragraph. Such claims shall comply with § 317.362(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as ''relative claims'' and include ''light,'' ''reduced,'' ''less'' (or ''fewer''), and ''more'' claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For ''less'' (or ''fewer'') and ''more'' claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For ''light,'' ''reduced,'' and ''added'' claims, the reference product shall be a similar product, and

(ii)(A) For ''light'' claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than ''light,'' including ''less'' and ''more'' claims, the reference product may be the same as that provided for ''light'' in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a

substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., ''50 percent less fat than 'reference product' '' or ''⅓ fewer calories than 'reference product' ''); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 317.2(h) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a ''low'' claim for that nutrient.

(k) The term ''modified'' may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., ''modified fat 'product' ''). This statement of identity must be immediately followed by the comparative statement such as ''contains 35 percent less fat than 'reference product' '' The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a ''meal-type'' product will be defined as a product that:

(1) Makes a major contribution to the diet by:

(i) Weighing at least 10 ounces per labeled serving; and

(ii) Containing not less than three 40 gram portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (l)(1)(ii)(A) through (D) of this section, that are in

the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in the form commonly understood to be, a breakfast, lunch, dinner, meal, or entre. Such representations may be made by statements, photographs, or vignettes.

(m) For purposes of making a claim, a main-dish product will be defined as a food that:

(1) Makes a major contribution to the meal by:

(i) Weighing at least 6 ounces per labeled serving; and

(ii) Containing not less than 40 grams of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (m)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (m)(l)(ii)(A) through (D) of this section, that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(3) Is represented as, or is in a form commonly understood to be, a main dish (*e.g.*, not a beverage or dessert). Such representations may be made by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with §317.309, shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with §317.309(h).

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in §317.312(b) through (e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by §317.312(f) (e.g., ''very low sodium, 35 mg or less per 55 grams'').

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by §317.2(h) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by §317.400(d)(2).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 1(n) of the Act (21 U.S.C. 601(n)(1)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in §317.309 may be made on the label or in the labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral.

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to §317.369.

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 40213, Aug. 8, 1994; 59 FR 45196, Sept. 1, 1994; 60 FR 187, Jan. 3, 1995; 69 FR 58801, Oct. 1, 2004]

§§ 317.314–317.343 [Reserved]

§ 317.344 Identification of major cuts of meat products.

The major cuts of single-ingredient, raw meat products are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round tip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small end, beef loin tenderloin steak, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets.

[58 FR 664, Jan. 6, 1993, as amended at 59 FR 45196, Sept. 1, 1994; 75 FR 82165, Dec. 29, 2010]

§ 317.345 Nutrition labeling of single-ingredient, raw meat products that are not ground or chopped products described in § 317.301.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw meat products identified in § 317.344, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 317.400. If nutrition information is presented on the label, it must be provided in accordance with § 317.309. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301 and are not major cuts of single-ingredient, raw meat products identified in § 317.344, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 317.309.

(3) A retailer may provide nutrition information at the point-of-purchase by various methods, such as by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 317.309 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 317.309 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 317.309(c)(8)) and footnote required by § 317.309(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 317.309(f).

(d) The nutrition label data for products covered in paragraphs (a)(1) and (a)(2) must be based on either the raw or cooked edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices. If data are based on cooked portions, the methods used to cook the products must be specified and for products covered in paragraphs (a)(1) and (a)(2) must be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the separable lean of meat cuts.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference, may be used for nutrition labeling of single-ingredient, raw meat products, including those that have been previously frozen. These

data may be composite data that reflect different quality grades of beef or other variables affecting nutrient content. Alternatively, data that reflect specific grades or other variables may be used, except that if data are used on labels attached to a product which is labeled as to grade of meat or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible meat tissues present in the package.

(f) If the nutrition information is provided in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 317.309(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw meat products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

[58 FR 664, Jan. 6, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 60 FR 189, Jan. 3, 1995; 75 FR 82165, Dec. 29, 2010]

§§ 317.346–317.353 [Reserved]

§ 317.354 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV) established for that nutrient (excluding total carbohydrate) in § 317.309(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *''High'' claims.* (1) The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), and main-dish products as defined in § 317.313(m) provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), and main-dish product as defined in § 317.313(m) provided that:

(i) The product contains a food that meets the definition of ''high'' in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of broccoli in this meal is high in vitamin C'').

(c) *''Good Source'' claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label or in labeling of products, except meal-type products as described in § 317.313(l), and main-dish products as defined in § 317.313(m) provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), and main-dish product as defined in § 317.313(m) provided that:

(i) The product contains a food that meets the definition of ''good source'' in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of sweet potatoes in this meal is a good source of fiber'').

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains ''more'' fiber, and the product is not ''low'' in total fat as defined in § 317.362(b)(2) or, in the case of a meal-type product or a main-dish product, is

not ''low'' in total fat as defined in § 317.362(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., ''contains 12 grams (g) of fat per serving''); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *''More'' claims.* (1) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 317.313(l), and main-dish products as defined in § 317.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber than 'reference product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving'').

(2) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 317.313(l), and main-dish products as defined in § 317.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product' ''), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product or a main-dish product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz'').

[60 FR 189, Jan. 3, 1995, as amended at 69 FR 58802, Oct. 1, 2004]

§ 317.355 [Reserved]

§ 317.356 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the terms ''light'' or ''lite'' to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *''Light'' claims.* The terms ''light'' or ''lite'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in § 317.313(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33⅓ percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 317.313(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 317.313(j)(1); and

(3) As required in § 317.313(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (e.g., ''⅓ fewer calories and 50 percent less fat than the market leader''); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving''); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A ''light'' claim may not be made on a product for which the reference product meets the definition of ''low fat'' and ''low calorie.''

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms ''light'' or ''lite'' without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving'').

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms ''light in sodium'' or ''lite in sodium'' if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that ''light'' or ''lite'' is presented in immediate proximity with ''in sodium'' and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or ''lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving'').

(3) Except for meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), a ''light in sodium'' claim may not be made on a product for which the reference product meets the definition of ''low in sodium.''

(d)(1) The terms ''light'' or ''lite'' may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product meets the definition of:

(A) ''Low in calories'' as defined in § 317.360(b)(3); or

(B) ''Low in fat'' as defined in § 317.362(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether ''light'' is used to mean ''low fat,'' ''low calories,'' or both (e.g., ''Light Delight, a low fat meal''); and

(B) The accompanying statement is no less than one-half the type size of the ''light'' or ''lite'' claim.

(2)(i) The terms ''light in sodium'' or ''lite in sodium'' may be used on the label or in labeling of a meal-type product as defined in §317.313(l) and main-dish product as defined in §317.313(m), provided that the product meets the definition of ''low in sodium'' as defined in §317.361(b)(5)(i); and

(ii) ''Light'' or ''lite'' and ''in sodium'' are presented in uniform type size, style, color, and prominence.

(3) The term ''light'' or ''lite'' may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is ''light in sodium'' or ''lite in sodium'' appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

(e) Except as provided in paragraphs (b) through (d) of this section, the terms ''light'' or ''lite'' may not be used to refer to a product that is not reduced in fat by 50 percent, or, if applicable, in calories by ⅓ or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the information (e.g., ''light in color'' or ''light in texture'') so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., ''color'' or ''texture'') is in the same style, color, and at least one-half the type size as the word ''light'' and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word ''light'' has been associated, through common use, with a particular product to reflect a physical or organoleptic attribute to the point where it has become part of the statement of identity, such use of the term ''light'' shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term ''lightly salted'' may be used on a product to which has been added 50 percent less sodium than is normally added to the reference product as described in §317.313(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not ''low in sodium'' as defined in §317.361(b)(4), the statement ''not a low sodium food,'' shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in §317.313(j)(2).

[60 FR 189, Jan. 3, 1995, as amended at 69 FR 58802, Oct. 1, 2004]

§§ 317.357–317.359 [Reserved]

§ 317.360 Nutrient content claims for calorie content.

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §317.313; and

(3) The product for which the claim is made is labeled in accordance with §317.309.

(b) *Calorie content claims.* (1) The terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of

calories'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low calorie,'' ''few calories,'' ''contains a small amount of calories,'' ''low source of calories,'' or ''low in calories'' may be used on the label or in labeling of products, except meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l) and main-dish product as defined in §317.313(m), provided that:

(i) The product contains 120 calories or less per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches.

(4) The terms ''reduced calorie,'' ''reduced in calories,'' ''calorie reduced,'' ''fewer calories,'' ''lower calorie,'' or ''lower in calories'' may be used on the label or in labeling of products, except meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in §317.313(j)(1); and

(ii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie 'product'—''33⅓ percent fewer calories than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 150 to 100 calories per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l) and main-dish product as defined in §317.313(m), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in §317.313(j)(1); and

(ii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction)

that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(c) *Sugar content claims.* (1) Terms such as ''sugar free,'' ''free of sugar,'' ''no sugar,'' ''zero sugar,'' ''without sugar,'' ''sugarless,'' ''trivial source of sugar,'' ''negligible source of sugar,'' or ''dietarily insignificant source of sugar'' may reasonably be expected to be regarded by consumers as terms that represent that the product contains no sugars or sweeteners, e.g., ''sugar free,'' or ''no sugar,'' as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in §317.309(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of sugars per labeled serving size;

(ii) The product contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sugar,'' ''adds a negligible amount of sugar,'' or ''adds a dietarily insignificant amount of sugar;'' and

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement ''not a reduced calorie product,'' ''not a low calorie product,'' or ''not for weight control.''

(2) The terms ''no added sugar,'' ''without added sugar,'' or ''no sugar added'' may be used only if:

(i) No amount of sugars, as defined in §317.309(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not ''low calorie'' or ''calorie reduced'' (unless the product meets the requirements for a ''low'' or ''reduced calorie'' product) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms ''reduced sugar,'' ''reduced in sugar,'' ''sugar reduced,'' ''less sugar,'' ''lower sugar,'' or ''lower in sugar'' may be used on the label or in labeling of products, except meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an

appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''this product contains 25 percent less sugar than our regular product''); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has been lowered from 8 g to 6 g per serving'').

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sugar 'product'—25% less sugar than our regular 'product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz'').

[60 FR 191, Jan. 3, 1995, as amended at 69 FR 58802, Oct. 1, 2004]

§ 317.361 Nutrient content claims for the sodium content.

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *Sodium content claims.* (1) The terms ''sodium free,'' ''free of sodium,'' ''no sodium,'' ''zero sodium,'' ''without sodium,'' ''trivial source of sodium,'' ''negligible source of sodium,'' or ''dietarily insignificant source of sodium'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sodium,'' ''adds a negligible amount of sodium'' or ''adds a dietarily insignificant amount of sodium''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''very low sodium'' or ''very low in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference

amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''low sodium,'' ''low in sodium,'' ''little sodium,'' ''contains a small amount of sodium,'' or ''low source of sodium'' may be used on the label and in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(6) The terms ''reduced sodium,'' ''reduced in sodium,'' ''sodium reduced,'' ''less sodium,'' ''lower sodium,'' or ''lower in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product', 50 percent less sodium than regular 'product' ''); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been lowered from 300 to 150 mg per serving'').

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low sodium.''

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product'—30% less sodium per 3 oz than our 'regular product' ''); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz'').

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for ''low sodium.''

(c) The term ''salt'' is not synonymous with ''sodium.'' Salt refers to sodium chloride. However, references to salt content such as ''unsalted,'' ''no salt,'' ''no salt added'' are potentially misleading.

(1) The term ''salt free'' may be used on the label or in labeling of products only if the product is ''sodium free'' as defined in paragraph (b)(1) of this section.

(2) The terms ''unsalted,'' ''without added salt,'' and ''no salt added'' may be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement, ''not a sodium free product'' or ''not for control of sodium in the diet'' appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

[60 FR 192, Jan. 3, 1995, as amended at 69 FR 58802, Oct. 1, 2004]

§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *Fat content claims.* (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''nonfat,'' ''trivial source of fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients,

which states: ''Adds a trivial amount of fat,'' ''adds a negligible amount of fat,'' or ''adds a dietarily insignificant amount of fat''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low fat,'' ''low in fat,'' ''contains a small amount of fat,'' ''low source of fat,'' or ''little fat'' may be used on the label and in labeling of products, except meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l) and main-dish product as defined in §317.313(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced fat,'' ''reduced in fat,'' ''fat reduced,'' ''less fat,'' ''lower fat,'' or ''lower in fat'' may be used on the label or in labeling of products, except meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in §317.313(j)(1); and

(ii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced fat—50 percent less fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g to 4 g per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l) and main-dish product as defined in §317.313(m), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in §317.313(j)(1); and

(ii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate

proximity to the most prominent such claim (e.g., ''reduced fat 'product', 33 percent less fat per 3 oz than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(6) The term ''_____ percent fat free'' may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for ''low fat'' in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words ''fat free'' are in uniform type size; and

(iii) A ''100 percent fat free'' claim may be made only on products that meet the criteria for ''fat free'' in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for ''_____ percent fat free'' is ''_____ percent lean.''

(c) *Fatty acid content claims.* (1) The terms ''saturated fat free,'' ''free of saturated fat,'' ''no saturated fat,'' ''zero saturated fat,'' ''without saturated fat,'' ''trivial source of saturated fat,'' ''negligible source of saturated fat,'' or ''dietarily insignificant source of saturated fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of saturated fat,'' ''adds a negligible amount of saturated fat,'' or ''adds a dietarily insignificant amount of saturated fat;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low in saturated fat,'' ''low saturated fat,'' ''contains a small amount of saturated fat,'' ''low source of saturated fat,'' or ''a little saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced saturated fat,'' ''reduced in saturated fat,'' ''saturated fat reduced,'' ''less saturated fat,'' ''lower saturated fat,'' or

''lower in saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat reduced from 3 g to 1.5 g per serving'').

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product','' ''50 percent less saturated fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz'').

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(d) *Cholesterol content claims.* (1) The terms ''cholesterol free,'' ''free of cholesterol,'' ''zero cholesterol,'' ''without cholesterol,'' ''no cholesterol,'' ''trivial source of cholesterol,'' ''negligible source of cholesterol,'' or ''dietarily insignificant source of cholesterol'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of cholesterol,'' ''adds a negligible amount of cholesterol,'' or ''adds a dietarily insignificant amount of cholesterol'';

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol

is reduced by 25 percent or more from the reference product it replaces as described in § 317.313(j)(1) and for which it substitutes as described in § 317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''cholesterol free 'product', contains 100 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''contains no cholesterol compared with 30 mg in one serving of 'reference product' '').

(2) The terms ''low in cholesterol,'' ''low cholesterol,'' ''contains a small amount of cholesterol,'' ''low source of cholesterol,'' or ''little cholesterol'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 317.313(j)(1) and for which it substitutes as described in § 317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''low cholesterol 'product', contains 85 percent less cholesterol than our regular 'product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 30 mg to 5 mg per serving'').

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l) and main-dish product as defined in § 317.313(m), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced cholesterol,'' ''reduced in cholesterol,'' ''cholesterol reduced,'' ''less cholesterol,'' ''lower cholesterol,'' or ''lower in cholesterol'' may be used on the label or in labeling of products or products that substitute for those products as specified in §317.313(d), excluding meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in §317.313(j)(1) and for which it substitutes as described in §317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 55 mg to 30 mg per serving'').

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l) and main-dish product as defined in §317.313(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in §317.313(j)(1) and for which it substitutes as described in §317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25% less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(e) *''Lean'' and ''Extra Lean'' claims.* (1) The term ''lean'' may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m).

(2) The term ''extra lean'' may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §317.313(l) and main-dish products as defined in §317.313(m).

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped meat products described in §317.301 when the product does not meet the criteria for

''low fat,'' defined in §317.362(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background, as the statement of the lean percentage.

[60 FR 193, Jan. 3, 1995, as amended at 69 FR 58802, Oct. 1, 2004; 75 FR 82165, Dec. 29, 2010]

§ 317.363 Nutrient content claims for "healthy."

(a) The term ''healthy,'' or any other derivative of the term ''health,'' may be used on the labeling of any meat or meat food product, provided that the product is labeled in accordance with §317.309 and §317.313.

(b)(1) The product shall meet the requirements for ''low fat'' and ''low saturated fat,'' as defined in §317.362, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for ''extra lean'' in §317.362.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in §317.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in §317.313(m), and a meal-type product, as defined in §317.313(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for ''extra lean''in §317.362.

(3) The product shall not contain more than 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in §317.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in §317.313(m), and a meal-type product, as defined in §317.313(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 600 mg of sodium per labeled serving size;[1] and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in §317.309 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A main-dish product, as defined in §317.313(m), and including main-dish products that weigh less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in §317.313(l), shall meet the level for three of the nutrients per labeled serving size.

[59 FR 24228, May 10, 1994, as amended at 60 FR 196, Jan. 3, 1995; 63 FR 7281, Feb. 13, 1998; 64 FR 72492, Dec. 28, 1999; 68 FR 463, Jan. 6, 2003; 69 FR 58802, Oct. 1, 2004; 71 FR 1686, Jan. 11, 2006]

§§ 317.364–317.368 [Reserved]

§ 317.369 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

[1] This regulation previously provided that, after January 1, 2006, individual meat products bearing the claim ''healthy'' (or any derivative of the term ''health'') must contain no more than 360 mg of sodium and that meal-type products bearing the claim ''healthy'' (or any other derivative of the term ''health'') must contain no more than 600 mg of sodium. Implementation of these sodium level requirements for products bearing the claim ''healthy'' (or any derivative of the term ''health'') has been deferred indefinitely due to technological barriers and consumer preferences.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250.

(Date)

The undersigned, _____, submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement

shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 317.309(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of meat and meat food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart B of part 317).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population,

the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the FEDERAL REGISTER a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the FEDERAL REGISTER seeking comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of meat food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after

review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a notice informing the public that the implied nutrient content claim has been approved for use.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088)

[58 FR 664, Jan. 6, 1993, as amended at 59 FR 45196, Sept. 1, 1994; 60 FR 196, Jan. 3, 1995]

§§ 317.370–317.379 [Reserved]

§ 317.380 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 317.309 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., ''Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s).''

(c) *''Low calorie'' foods.* A product purporting to be ''low calorie'' must comply with the criteria set forth for such foods in § 317.360.

(d) *''Reduced calorie'' foods and other comparative claims.* A product purporting to be ''reduced calorie'' or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 317.360(b) (4) and (5).

(e) *''Label terms suggesting usefulness as low calorie or reduced calorie foods''.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as ''diet,'' ''dietetic,'' ''artificially sweetened,'' or ''sweetened with nonnutritive sweetener'' only if the claim is not false or misleading, and the product is labeled ''low calorie'' or ''reduced calorie'' or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term ''diet'' that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., ''for low sodium diets.''

(3) Paragraph (e)(1) of this section shall not apply to any use of such

terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) *''Sugar free'' and ''no added sugar''.* Criteria for the use of the terms ''sugar free'' and ''no added sugar'' are provided for in §317.360(c).

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 58 FR 66075, Dec. 17, 1993; 60 FR 196, Jan. 3, 1995]

§§ 317.381–317.399 [Reserved]

§ 317.400 Exemption from nutrition labeling.

(a) The following meat or meat food products are exempt from nutrition labeling:

(1) Food products produced by small businesses, other than the major cuts of single-ingredient, raw meat products identified in §317.344 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in §317.301 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with §317.362(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

(i) A food product, for the purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility, including a single retail store, or multi-plant company/firm, including a multi-retail store operation, that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to ready-to-eat ground or chopped meat products described in §317.301 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under (a)(1);

(ii) Multi-ingredient products (e.g., sausage) processed at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to multi-ingredient ground or chopped meat products described in §317.301 that are processed at a retail establishment, unless the establishment qualifies for an exemption under (a)(1); and

(iii) Products that are ground or chopped at an individual customer's request.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling as provided in paragraph (c)(2) of this section, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol.

(2) Foods represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling except that:

(i) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;

(ii) Nutrient names and quantitative amounts by weight shall be presented in two separate columns;

(iii) The heading ''Percent Daily Value'' required in §317.309(d)(6) shall be placed immediately below the quantitative information by weight for protein;

(iv) The percent of the Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading ''Percent Daily Value''; and

(v) Such labeling shall not include the footnote specified in §317.309(d)(9).

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information, except that this exemption does not apply to the major cuts of single-ingredient, raw meat products identified in §317.344. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., ''For nutrition information call 1–800–123–4567'').

(2) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in a type size no smaller than 6 point or all upper case type of 1/16-inch minimum height, except that individual serving-size packages of meat products that have a total area available to bear labeling of 3 square inches or less may provide all required information in a type size no smaller than 1/32-inch minimum height.

[58 FR 664, Jan. 6, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 196, Jan. 3, 1995; 75 FR 82165, Dec. 29, 2010]

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

Subpart A—General

Sec.

Subparts B–G [Reserved]

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

Subpart A—General

SOURCE: 35 FR 15586, Oct. 3, 1970, unless otherwise noted.

§ 318.1 Products and other articles entering official establishments.

(a) Except as otherwise provided in paragraphs (g) and (h) of this section or § 318.12, no product shall be brought into an official establishment unless it has been prepared only in an official establishment and previously inspected and passed by a Program employee, and is identified by an official inspection legend as so inspected and passed. Notwithstanding the foregoing provisions of this subparagraph, product imported in accordance with part 327 of this subchapter and not prepared in the United States outside an official establishment, may enter any official establishment subject in other respects to the same restrictions as apply to domestic product. Products received in an official establishment during the Program employees absence shall be identified and maintained in a manner acceptable to such employee. Product entering any official establishment shall not be used or prepared thereat until it has been reinspected in accordance with § 318.2. Any product originally prepared at any official establishment may not be returned into any part of such establishment, except the receiving area approved under § 318.3, until it has been reinspected by the inspector.

(b) No slaughtered poultry or poultry product shall be brought into an official establishment unless it has been (1) previously inspected and passed and is identified as such in accordance with the requirements of the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) and the regulations thereunder, and has not been prepared other than in an establishment inspected under said Act, or (2) has been inspected and passed and is identified as such in accordance with the requirements of a State law.

(c) Every article for use as an ingredient in the preparation of meat food products, when entering any official establishment and at all times while it is in such establishment, shall bear a label showing the name of the article, the amount or percentage therein of any substances restricted by this part or part 317 of this subchapter, and a list of ingredients in the article if composed of two or more ingredients: *Provided*, That in the case of articles received in tank car lots, only one such label shall be used to identify each lot. In addition, the label must show the name and address of the shipper.

(d) To ensure the safe use of preparations used in hog scalding water or in the denuding of tripe, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B, or 9 CFR Chapter III, Subchapter A or Subchapter E.

(e) Dyes, chemicals, or other substances the use of which is restricted to certain products may be brought into or kept in an official establishment only if such products are prepared thereat. No prohibited dye, chemical, preservative, or other substance shall be brought into or kept in an official establishment.

(f) [Reserved]

(g) Glands and organs, such as cotyledons, ovaries, prostate glands, tonsils, spinal cords, and detached lymphatic, pineal, pituitary, parathyroid, suprarenal, pancreatic and thyroid glands, used in preparing pharmaceutical, organotherapeutic, or technical products and which are not used as human food (whether or not prepared at official establishments) may be brought into and stored in edible

product departments of inspected establishments if packaged in suitable containers so that the presence of such glands and organ will in no way interfere with the maintenance of sanitary conditions or constitute an interference with inspection. Glands or organs which are regarded as human food products, such as livers, testicles, and thymus glands, may be brought into official establishments for pharmaceutical, organotherapeutic or technical purposes, only if U.S. inspected and passed and so identified. Lungs and lung lobes derived from livestock slaughtered in any establishment may not be brought into any official establishment except as provided in § 318.12(a).

(h)(1) Carcasses of game animals, and carcasses derived from the slaughter by any person of livestock of his own raising in accordance with the exemption provisions of paragraph 23(a) of the Act, and parts of such carcasses, may be brought into an official establishment for preparation, packaging, and storing in accordance with the provisions of § 303.1(a)(2) of this subchapter.

(2) Meat, meat byproducts, and meat food products bearing official marks showing that they were inspected and passed under State inspection in any State not designated in § 331.2 of this subchapter may be received by official establishments for storage and distribution solely in intrastate commerce. The presence of such State inspected products must not create any unsanitary condition or otherwise result in adulteration of any products at the official establishment or interfere with the conduct of inspection under this subchapter. In addition, such State inspected products must be stored separately and apart from the federally inspected products in the official establishment.

(i) The operator of the official establishment shall furnish such information as is necessary to determine the origin of any product or other article entering the official establishment. Such information shall include, but is not limited to, the name and address of the seller or supplier, transportation company, agent, or broker involved in the sale or delivery of the product or article in question.

(j) Any product or any poultry or poultry product or other article that is brought into an official establishment contrary to any provision of this section may be required by the Administrator to be removed immediately from such establishment by the operator thereof, and failure to comply with such requirement shall be deemed a violation of this regulation. If any slaughtered poultry or poultry products or other articles are received at an official establishment and are suspected of being adulterated or misbranded under the Poultry Products Inspection Act or the Federal Food, Drug, and Cosmetic Act, or applicable State laws, the appropriate governmental authorities will be notified.

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 38 FR 5152, Feb. 26, 1973; 48 FR 6091, Feb. 10, 1983; 49 FR 32055, Aug. 10, 1984; 64 FR 72174, Dec. 23, 1999]

§ 318.2 Reinspection, retention, and disposal of meat and poultry products at official establishments.

(a) All products and all slaughtered poultry and poultry products brought into any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment and shall be subject to reinspection by a Program employee at the official establishment in such manner and at such times as may be deemed necessary to assure compliance with the regulations in this subchapter.

(b) All products, whether fresh, cured, or otherwise prepared, even though previously inspected and passed, shall be reinspected by Program employees as often as they may deem necessary in order to ascertain that they are not adulterated or misbranded at the time they enter or leave official establishments and that the requirements of the regulations in this subchapter are complied with.

(c) Reinspection may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The circuit supervisor shall designate the type of plan and the program employee shall select the specific plan to be used in

accordance with instructions issued by the Administrator.[1]

(d) A U.S. retained tag shall be placed by a Program employee at the time of reinspection at any official establishment on all products which are suspected on such reinspection of being adulterated or misbranded, and such products shall be held for further inspection. Such tags shall be removed only by authorized Program employees. When further inspection is made, if the product is found to be adulterated, all official inspection legends or other official marks for which the product is found to be ineligible under the regulations in this subchapter, shall be removed or defaced and the product will be subject to condemnation and disposal in accordance with part 314 of this subchapter, except that a determination regarding adulteration may be deferred if a product has become soiled or unclean by falling on the floor or in any other accidental way or if the product is affected with any other condition which the inspector deems capable of correction, in which case the product shall be cleaned (including trimming if necessary) or otherwise handled in a manner approved by the inspector to assure that it will not be adulterated or misbranded and shall then be presented for reinspection and disposal in accordance with this section. If upon final inspection, the product is found to be neither adulterated nor misbranded, the inspector shall remove the U.S. retained tag. If a product is found upon reinspection to be misbranded, it shall be held under a U.S. retained tag, or a U.S. detention tag as provided in part 329 of this subchapter, pending correction of the misbranding or issuance of an order under section 7 of the Act to withhold from use the labeling or container of the product, or the institution of a judicial seizure action under section 403 of Act or other appropriate action. The inspector shall make a complete record of each transaction under this paragraph and shall report his action to the area supervisor.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 318.3 Designation of places of receipt of products and other articles for reinspection.

Every official establishment shall designate, with the approval of the circuit supervisor, a dock or place at which products and other articles subject to reinspection under § 318.2 shall be received, and such products and articles shall be received only at such dock or place.

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

(a) All processes used in curing, pickling, rendering, canning, or otherwise preparing any product in official establishments shall be supervised by Program employees unless such preparation is conducted as a custom operation exempted from inspection under § 303.1(a)(2) of this subchapter in any official establishment or consists of operations that are exempted from inspection under § 303.1(d) of this subchapter and are conducted in a retail store in an establishment subject to inspection only because the State or Territory in which the establishment is located is designated under paragraph 301(c) of the Act. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the

[1] Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisors of Program circuits. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved, such as liver, oxtails, etc.

regulations in this subchapter. In order to carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to assure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter. The effectiveness of such measures will be subject to review by the Department.

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing meat food product who has a total plant quality control system or plan for controlling such product, after antemortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner of operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control system requires it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of an establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will be responsible for the quality control system.

(3) A list identifying those parts and sections of the Federal meat inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the quality control system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters or limits which will be used, and the points at which corrective action will occur and the nature of such corrective action—ranging from least to most severe: *Provided,* That, subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) [Reserved]

(e) *Evaluation and Approval of Total Plant Quality Control.* (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section. If it is determined by the Administrator,

on the basis of the evaluation, that the total quality control system will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with the notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities under the Act.

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section may only use, as a part of any label, the following logo.

(g) *Termination of Total Plant Quality Control.* (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where

there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(h)(1) *Operating Schedule Under Total Plant Quality Control.* An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permission will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in § 318.4(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspection services at the discretion of the circuit supervisor and charged for such services.

(Reporting requirements were approved by the Office of Management and Budget under control number 0583–0015)

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 12003, June 24, 1971; 45 FR 54322, Aug. 15, 1980; 51 FR 32304, Sept. 11, 1986; 62 FR 45024, Aug. 25, 1997; 62 FR 54759, Oct. 22, 1997; 65 FR 34389, May 30, 2000; 78 FR 66837, Nov. 7, 2013]

§ 318.5 Requirements concerning procedures.

(a)(1) Care shall be taken to assure that product is not adulterated when placed in freezers. If there is doubt as to the soundness of any frozen product, the inspector will require the defrosting and reinspection of a sufficient quantity thereof to determine its actual condition.

(2) Frozen product may be defrosted in water or pickle in a manner and with the use of facilities which are acceptable to the inspector. Before such product is defrosted, a careful examination shall be made to determine its condition. If necessary, this examination shall include defrosting of representative samples by means other than in water or pickle.

(b) Product, such as pork tenderloins, brains, sweetbreads, stew, or chop suey, shall not be packed in hermetically sealed metal or glass containers, unless subsequently heat processed or otherwise treated to preserve the product in a manner approved by the Administrator in specific cases.

(c) Care shall be taken to remove bones and parts of bones from product which is intended for chopping.

(d) Heads for use in the preparation of meat food products shall be split and the bodies of the teeth, the turbinated and ethmoid bones, ear tubes, and horn butts removed, and the heads then thoroughly cleaned.

(e) Kidneys for use in the preparation of meat food products shall first be freely sectioned and then thoroughly soaked and washed. All detached kidneys, including beef kidneys with detached kidney fat, shall be inspected before being used in or shipped from the official establishment.

(f) Cattle paunches and hog stomachs for use in the preparation of meat food products shall be thoroughly cleaned

on all surfaces and parts immediately after being emptied of their contents, which shall follow promptly their removal from the carcasses.

(g) Clotted blood shall be removed from hog hearts before they are shipped from the official establishment or used in the preparation of meat food products.

(h) Beef rounds, beef bungs, beef middles, beef bladders, calf rounds, hog bungs, hog middles, and hog stomachs which are to be used as containers of any meat food product shall be presented for inspection, turned with the fat surface exposed.

(i) Portions of casings which show infection with Oesophagostomum or other nodule-producing parasite, and weasands infected with the larvae of Hypoderma lineatum, shall be rejected, except that when the infestation is slight and the nodules and larvae are removed, the casing or weasand may be passed.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 318.6 Requirements concerning ingredients and other articles used in preparation of products.

(a) All ingredients and other articles used in the preparation of any product shall be clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated. Official establishments shall furnish inspectors accurate information on all procedures involved in product preparation including product composition and any changes in such procedures essential for inspectional control of the product.

(b)(1) The only animal casings that may be used as containers of product are those from sheep, swine, or goats. Casings from cattle may be used as containers of products. However, if casings from cattle are derived from the small intestine, the small intestine must comply with the requirements in 9 CFR 310.22(d). Establishments that use casings derived from the small intestine of cattle as containers for products must demonstrate, through documentation, that the small intestine from which the casing was derived complies with the requirements in 9 CFR 310.22(d).

(2) Casings for products shall be carefully inspected by Program employees. Only those casings which have been carefully washed and thoroughly flushed with clean water immediately before stuffing and are suitable for containers, are clean, and are passed on such inspection shall be used, except that preflushed animal casings packed in salt or salt and glycerine solution or other approved medium may be used without additional flushing provided they are found to be clean and otherwise acceptable and are thoroughly rinsed before use.

(3) Hog and sheep casings intended for use as containers of product may be treated by soaking in or applying thereto sound, fresh pineapple juice or papain or bromelin or pancreatic extract to permit the enzymes contained in these substances to act on the casings to make them less resistant. The casings shall be handled in a clean and sanitary manner throughout and the treatment shall be followed by washing and flushing the casings with water sufficiently to effectively remove the substance used and terminate the enzymatic action.

(4) On account of the invariable presence of bone splinters, detached spinal cords shall not be used in the preparation of edible product other than for rendering where they constitute a suitable raw material. Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering.

(5) Testicles if handled as an edible product may be shipped from the official establishment as such, but they shall not be used as an ingredient of a meat food product.

(6) Tonsils shall be removed and shall not be used as ingredients of meat food products.

(7) Blood from livestock prepared in accordance with §310.20 of this subchapter may be used as an ingredient of a meat food product for which a standard is prescribed in part 319 of this subchapter, if permitted by such standard, and may be used in any meat food product for which no such standard is prescribed in part 319 of this subchapter if it is a common and usual ingredient of such product.

(8) Intestines shall not be used as ingredients in any meat food product for which a standard is prescribed in part 319 of this subchapter and shall not be used in other products unless the products are labeled in accordance with § 317.8(b)(3) of this subchapter. When small intestine from cattle is used in a meat food product or for edible rendering, it must comply with the requirements in 9 CFR 310.22(d).

(9) Poultry products and egg products (other than shell eggs) which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when identified as having been inspected and passed for wholesomeness by the Department under the regulations in 7 CFR part 59 or 9 CFR part 362 or 381 and when found to be sound and otherwise acceptable when presented for use. Poultry products and egg products (other than shell eggs) which have not been so inspected and passed for wholesomeness shall not be used in the preparation of such meat food products.

(10) Dry milk products which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when produced in a plant approved by the Department under the regulations in 7 CFR part 58, and when found to be sound and otherwise acceptable when presented for use. Dry milk products prepared in a plant not so approved shall not be used in the preparation of such meat food products.

(11) [Reserved]

(12) Ingredients for use in any product may not bear or contain any pesticide chemical or other residues in excess of level permitted in § 318.16.

(13) Use of ''Mechanically Separated (Kind of Poultry),'' as defined in § 381.173 of this chapter, in the preparation of meat food products shall accord with § 381.174 and all other applicable provisions of this subchapter.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 14368, June 1, 1973; 38 FR 29214, Oct. 23, 1973; 39 FR 1973, Jan. 16, 1974; 41 FR 23702, June 11, 1976; 49 FR 19623, May 9, 1984; 50 FR 6, Jan. 2, 1985; 60 FR 55982, Nov. 3, 1995; 69 FR 1874, Jan. 12, 2004; 70 FR 53050, Sept. 7, 2005; 72 FR 38730, July 13, 2007]

§ 318.8 Preservatives and other substances permitted in product for export only; handling; such product not to be used for domestic food purposes.

(a) Preservatives and other substances not permitted in domestic product under the regulations in this subchapter may be used in the preparation and packing of product intended for export provided the product (1) accords to the specifications or directions of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; and (3) is labeled on the outside container to show that it is intended for export, and is otherwise labeled as required by this subchapter for such export product.

(b) The preparation and packing of export product as provided for in paragraph (a) of this section shall be done in a manner acceptable to the inspector in charge so that the identity of the export product is maintained conclusively and the preparation of domestic product is adequately protected. The preservatives and other substances not permitted in domestic product shall be stored in a room or compartment separate from areas used to store other supplies and shall be held under Program lock. Use of the preservatives or other substances shall be under the direct supervision of a Program employee.

(c) The packing of all articles under paragraph (a) of this section shall be conducted under the direct supervision of a Program employee.

(d) No article prepared or packed for export under paragraph (a) of this section shall be sold or offered for sale for domestic use or consumption, but unless exported shall be destroyed for food purposes under the direct supervision of a Program employee.

(e) The contents of the container of any article prepared or packed for export under paragraph (a) of this section shall not be removed, in whole or in part, from such container prior to exportation, except under the supervision of a Program employee. If such contents are removed prior to exportation, then the article shall be either repacked, in accordance with the provisions of paragraphs (b) and (c) of this

section, or destroyed for food purposes under the direct supervision of a Program employee.

(f) Permission must be obtained from the Administrator before meats packed in borax are shipped from one official establishment to another or to an unofficial establishment for storage, except such meat prepared for the account of Federal agencies.

(g) At all times, the identity of meat to which borax has been added shall be effectively maintained. In no case shall such meat, nor any trimmings or fat derived from such meat, whether unwashed or washed, or otherwise treated, be diverted to domestic use.

(h) Salt used for bulking meat previously packed in borax may not again be used in an edible products department other than in connection with the packing of meat in borax. Only metal equipment should be used for handling such meat. Particularly effective cleansing will be required if wooden equipment such as trucks, washing vats, etc., is used. Boxes from which boraxed meat has been removed may be used for repacking meat in borax, but their use as containers for other meat will be dependent upon the effective removal of all traces of borax.

(i) The following instructions pertain to export cured pork packed in borax for the account of Federal agencies. The meat may be packed in borax in a room in which there is borax-free meat, provided proper care is taken to see that the borax-free meat is not affected by the borax. Under the same condition, meat packed in borax may be received, unpacked, defrosted, soaked, washed, smoked, and repacked in a room where there is other meat. However, meat originally packed in borax shall at all times be subject to the restrictions of meat so packed, even though repacked without borax. After packing or repacking, borax packed meat may be stored in a room with meat not packed in borax, provided a reasonable degree of separation is maintained between the two classes of product.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 38 FR 29214, Oct. 23, 1973]

§ 318.9 Samples of products, water, dyes, chemicals, etc., to be taken for examination.

Samples of products, water, dyes, chemicals, preservatives, spices, or other articles in any official establishment shall be taken, without cost to the Program, for examination, as often as may be deemed necessary for the efficient conduct of the inspection.

§ 318.10 [Reserved]

§ 318.11 [Reserved]

§ 318.12 Manufacture of dog food or similar uninspected article at official establishments.

(a) When dog food, or similar uninspected article is manufactured in an edible product department, there shall be sufficient space allotted and adequate equipment provided so that the manufacture of the uninspected article in no way interferes with the handling or preparation of edible products. Where necessary to avoid adulteration of edible products, separate equipment shall be provided for the uninspected article. To assure the maintenance of sanitary conditions in the edible product departments, the operations incident to the manufacture of the uninspected article will be subject to the same sanitary requirements that apply to all operations in edible product departments. The manufacture of the uninspected article shall be limited to those hours during which the establishment operates under inspectional supervision; and there shall be no handling, other than receiving at the official establishment, of any of the product ingredient of the uninspected article, other than during the regular hours of inspection. The materials used in the manufacture of the uninspected article shall not be used so as to interfere with the inspection of edible product or the maintenance of sanitary conditions in the department or render any edible product adulterated. The meat, meat byproducts, and meat food product ingredients of the uninspected article may be admitted into any edible products department of an official establishment only if they are U.S. Inspected and Passed. Products within §314.11 of this subchapter or parts of carcasses of kinds not permitted under

the regulations in this subchapter to be prepared for human food (e.g., lungs or intestines), which are produced at any official establishment, may be brought into the inedible products department of any official establishment for use in uninspected articles under this section. The uninspected article may be stored in, and distributed from, edible product departments: *Provided*, That adequate facilities are furnished, there is no interference with the maintenance of sanitary conditions, and such article is properly identified.

(b) When dog food or similar uninspected article is manufactured in a part of an official establishment other than an edible product department, the area in which the article is manufactured shall be separated from edible product departments in the manner required for separation between edible product departments and inedible product departments. Sufficient space must be allotted and adequate equipment provided so that the manufacture of the uninspected article does not interfere with the proper functioning of the other operations at the establishment. Except as provided in §314.11 of this subchapter, nothing in this paragraph shall be construed as permitting any deviation from the requirement that dead animals, condemned products, and similar materials of whatever origin, must be placed in the inedible product rendering equipment, and without undue delay. The manufacture of the uninspected article must be such as not to interfere with the maintenance of general sanitary conditions on the premises, and it shall be subject to inspectional supervision similar to that exercised over other inedible product departments. There shall be no movement of any product from an inedible product department to any edible product department. Trucks, barrels, and other equipment shall be cleaned before being returned to edible product departments from inedible product departments. Unoffensive material prepared outside edible product departments may be stored in, and distributed from, edible product departments only if packaged in clean, properly identified, sealed containers.

(c) Animal food shall be distinguished from articles of human food, so as to avoid distribution of such animal food as human food. To accomplish this, such animal food shall be labeled or otherwise identified in accordance with §325.11(d) of this subchapter.

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 53 FR 24679, June 30, 1988]

§ 318.13 Mixtures containing product but not amendable to the Act.

Mixtures containing product but not classed as a meat food product under the Act shall not bear the inspection legend or any abbreviation or representation thereof unless manufactured under the food inspection service provided for in part 350 of subchapter B of this chapter. When such mixtures are manufactured in any part of an official establishment, the sanitation of that part of the establishment shall be supervised by Program employees, and the manufacture of such mixtures shall not cause any deviation from the requirement of §318.1.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973]

§ 318.14 Adulteration of product by polluted water; procedure for handling.

(a) In the event there is polluted water (including but not limited to flood water) in an official establishment, all products and ingredients for use in the preparation of such products that have been rendered adulterated by the water shall be condemned.

(b) After the polluted water has receded from an official establishment, all walls, ceilings, posts, and floors of the rooms and compartments involved, including the equipment therein, shall, under the supervision of an inspector, be cleaned thoroughly by the official establishment personnel. An adequate supply of hot water under pressure is essential to make such cleaning effective. After cleaning, a solution of sodium hypochlorite containing approximately one-half of 1 percent available chlorine (5,000 p/m) or other equivalent disinfectant approved by the Administrator[1] shall be applied to the surface of the rooms and equipment and rinsed with potable water before use.

(c) Hermetically sealed containers of product which have been contaminated by polluted water shall be examined

promptly by the official establishment under supervision of an inspector and rehandled as follows:

(1) Separate and condemn all product in damaged or extensively rusted containers.

(2) Remove paper labels and wash the remaining containers in warm soapy water, using a brush where necessary to remove rust or other foreign material. Disinfect these containers by either of the following methods:

(i) Immerse in a solution of sodium hypochlorite containing not less than 100 p/m of available chlorine or other equivalent disinfectant approved by the Administrator,[1] rinse in potable water, and dry thoroughly; or

(ii) Immerse in 212 °F. water, bring temperature of the water back to 212 °F. and maintain the temperature at 212 °F. for 5 minutes, then remove containers from water and cool them to 95 °F. and dry thoroughly.

(3) After handling as described in paragraph (c)(2) of this section, the containers may be relacquered, if necessary, and then relabeled with approved labels applicable to the product therein.

(4) The identity of the canned product shall be maintained throughout all stages of the rehandling operations to insure correct labeling of the containers.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 34455, Dec. 14, 1973]

§ 318.15 Tagging chemicals, preservatives, cereals, spices, etc., "U.S. retained."

When any chemical, preservative, cereal, spice, or other substance is intended for use in an official establishment, it shall be examined by a Program employee and if found to be unfit or otherwise unacceptable for the use intended, or if final decision regarding acceptance is deferred pending laboratory or other examination, the employee shall attach a ''U.S. retained'' tag to the substance or container thereof. The substance so tagged shall be kept separate from other substances as the circuit supervisor may require and shall not be used until the tag is removed, and such removal shall be made only by a Program employee after a finding that the substance can be accepted, or, in the case of an unacceptable substance, when it is removed from the establishment.

§ 318.16 Pesticide chemicals and other residues in products.

(a) *Nonmeat ingredients.* Residues of pesticide chemicals, food additives and color additives or other substances in or on ingredients (other than meat, meat byproducts, and meat food products) used in the formulation of products shall not exceed the levels permitted under the Federal Food, Drug, and Cosmetic Act, and such nonmeat ingredients must otherwise be in compliance with the requirements under that Act.

(b) *Products, and meat, meat byproduct, or other meat food product ingredients.* Products, and products used as ingredients of products, shall not bear or contain any pesticide chemical, food additives, or color additive residue in excess of the level permitted under the Federal Food, Drug, and Cosmetic Act and the regulations in this subchapter, or any other substance that is prohibited by such regulations or that otherwise makes the products adulterated.

(c) *Standards and procedures.* Instructions specifying the standards and procedures for determining when ingredients of finished products are in compliance with this section shall be issued to the inspectors by the Administrator. Copies of such instructions will be made available to interested persons upon request made to the Administrator.

§ 318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.

(a) Cooked beef, roast beef, and cooked corned beef products must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality.* A 6.5-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability

[1] A list of approved disinfectants is available upon request to Scientific Services, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) *Stabilization.* There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum,* and no more than 1-$\log_{10}$ multiplication of *Clostridium perfringens* within the product.

(b) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file and available to FSIS, a process schedule, as defined in § 301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to the establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(c) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

[64 FR 744, Jan. 6, 1999]

§ 318.18 Handling of certain material for mechanical processing.

Material to be processed into ''Mechanically Separated (Species)'' shall be so processed within 1 hour from the time it is cut or separated from carcasses or parts of carcasses, except that such product may be held for no more than 72 hours at 40 °F. (4 °C.) or less, or held indefinitely at 0 °F. (−18 °C.) or less. ''Mechanically Separated (Species)'' shall, directly after being processed, be used as an ingredient in a meat food product except that it may be held prior to such use for no more than 72 hours at 40 °F. (4 °C.) or less or indefinitely at 0 °F. (−18 °C.) or less.

[43 FR 26423, June 20, 1978, as amended at 47 FR 28256, June 29, 1982]

§ 318.19 Compliance procedure for cured pork products.

(a) *Definitions.* For the purposes of this section:

(1) A *product* is that cured pork article which is contained within one *Group* as defined in paragraph (a)(2) of this section and which purports to meet the criteria for a single product designated under the heading ''Product Name and Qualifying Statements'' in the chart in § 319.104 or the chart in § 319.105.

(2) A *Product Group* or a *Group* means one of the following:

Group I, consisting of cured pork products which have been cooked while imperviously encased. Any product which fits into the Group will be placed in this Group regardless of any other considerations.

Group II, consisting of cured pork products which have been water cooked. Any product which does not fit into Group I but does fit into Group II will be placed into Group II regardless of any other considerations.

Group III, consisting of boneless smokehouse heated cured pork products. Any boneless product that does not fit into Group I or Group II shall be placed in Group III.

Group IV, consisting of bone-in or semi-boneless smokehouse heated cured pork products. Any product that is not completely boneless or still contains all the bone which is traditional for bone-in product, and does not fit into Group I, Group II, or Group III shall be placed in this Group.

(3) A *lot* is that product from one production shift.

(4) A *production rate* is frequency of production, expressed in days per week.

(5) *Protein fat free percentage, protein fat free content, PFF percentage, PFF content or PFF* of a product means the meat protein (indigenous to the raw, unprocessed pork cut) content expressed as a percent of the non-fat portion of the finished product.

(b) *Normal Compliance Procedures.* The Department shall collect samples of cured pork products and analyze them for their PFF content. Analyses shall be conducted in accordance with the ''Official Methods of Analysis of the Association of Official Analytical Chemists §§ 950.46, and 928.08 (Chapter

39).[1] The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Each analytical result shall be recorded and evaluated to determine whether future sampling of product Groups within an official establishment shall be periodic or daily under the provisions of paragraph (b)(1) of this section, and if the affected lot and subsequent production of like product shall be U.S. retained, or administratively detained, as appropriate, as provided in paragraph (b)(2) of this section.[2]

(1) *Criteria to determine sampling frequency of Product Groups.* For each official plant preparing cured pork products, Product Groups shall be sampled periodically or daily. Analytical results shall be evaluated and the sampling frequency determined as follows:

(i) Determine the difference between the individual PFF analysis and the applicable minimum PFF percentage requirement of §319.104 or §319.105. The resulting figure shall be negative when the individual sample result is less than the applicable minimum PFF percentage requirement and shall be positive when the individual sample result is greater than the applicable minimum PFF percentage requirement.

(ii) Divide the resulting number by the standard deviation assigned to the Product Group represented by the sample to find the Standardized Difference. The standard deviation assigned to Groups I and II is 0.75 and to Groups III and IV is 0.91.

(iii) Add 0.25 to the Standardized Difference to find the Adjusted Standardized Difference.

(iv) Use the lesser of 1.90 and the Adjusted Standardized Difference as the Sample Value.

(v) Cumulatively total Sample Values to determine the Group Value. The first Sample Value in a Group shall be the Group Value, and each succeeding Group Value shall be determined by adding the most recent Sample Value to the existing Group Value; provided, however, that in no event shall the Group Value exceed 1.00. When calculation of a Group Value results in a figure greater than 1.00, the Group Value shall be 1.00 and all previous Sample Values shall be ignored in determining future Group Values.

(vi) The frequency of sampling of a Group shall be periodic when the Group Value is greater than −1.40 (e.g., −1.39, −1.14, 0, 0.50, etc.) and shall be daily when the Group Value is −1.40 or less (e.g., −1.40, −1.45, −1.50, etc.); provided, however, that once daily sampling has been initiated, it shall continue until the Group Value is 0.00 or greater, and each of the last seven Sample Values is −1.65 or greater (e.g., −1.63, −1.50, etc.), and there is no other product within the affected Group being U.S. retained as produced, under provisions of paragraph (b)(2) or (c).

(2) *Criteria for U.S. retention or administrative detention of cured pork products*

[1] A copy of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

[2] Rules for Rounding:

1. Laboratory results for percent meat protein and fat will be reported to the second decimal place (hundredths).

2. PFF and Sample Values for charting purposes will be calculated from the reported laboratory results to the second decimal place. Rounding of calculations to reach two decimal places will be done by the following rule:

All values of five-thousandths (0.005) or more will be rounded up to the next highest hundredth. All values of less than five-thousandths (0.005) will be dropped.

3. For compliance with the Absolute Minimum PFF requirements, the PFF will be rounded to the first decimal place (tenths). Rounding of calculations to reach one decimal place will be done by the following rule:

All PFF values of five-hundredths (0.05) or more will be rounded up to the next highest tenth. All PFF values of less than five-hundredths (0.05) will be dropped.

4. For product disposition (pass-fail of a minimum PFF standard for retained product) the average PFF calculation will be rounded to the first decimal place. Individual PFF Values will be calculated to the nearest hundredth as in (2) above. The average, however, will be rounded to the nearest tenth as in (3) above.

for further analysis. Cured prok products shall be U.S. retained, or administratively detained, as appropriate, when prescribed by paragraphs (b)(2) (i) or (ii) of this section as follows:

(i) *Absolute Minimum PFF Requirement.* In the event that an analysis of an individual sample indicates a PFF content below the applicable minimum requirement of §319.104 or §319.105 by 2.3 or more percentage points for a Group I or II product, or 2.7 or more percentage points for a Group III or IV product, the lot from which the sample was collected shall be U.S. retained if in an official establishment and shall be subject to administrative detention if not in an official establishment unless returned to an official establishment and there U.S. retained. Any subsequently produced lots of like product and any lots of like product for which production dates cannot be established shall be U.S. retained or subject to administrative detention. Such administratively detained product shall be handled in accordance with part 329 of this subchapter, or shall be returned to an official establishment and subjected to the provisions of paragraph (c)(1) (i) or (ii) of this section, or shall be relabeled in compliance with the applicable standard, under the supervision of a program employee, at the expense of the product owner. Disposition of such U.S. retained product shall be in accordance with paragraph (c) of this section.

(ii) *Product Value requirement.* The Department shall maintain, for each product prepared in an official establishment, a Product Value. Except as provided in paragraph (c)(2) of this section, calculation of the Product Value and its use to determine if a product shall be U.S. retained shall be as follows:

(A) Determine the difference between the individual PFF analysis and applicable minimum PFF percentage requirement of §319.104 and §319.105. The resulting figure shall be negative when the individual sample result is less than the applicable minimum PFF percentage requirement and shall be positive when the individual sample result is greater than the applicable minimum PFF percentage requirement.

(B) Divide the difference determined in paragraph (b)(2)(ii)(A) of this section by the standard deviation assigned to the product's Group in paragraph (b)(1)(ii) of this section to find the standardized difference.

(C) Use the lesser of 1.65 and the standardized difference as the Sample Value.

(D) Cumulatively total Sample Values to determine the Product Value. The first Sample Value of a product shall be the Product Value, and each succeeding Product Value shall be determined by adding the most recent Sample Value to the existing Product Value; provided, however, that in no event shall the Product Value exceed 1.15. When calculation of a Product Value results in a figure greater than 1.15, the Product Value shall be 1.15, and all previous Sample Values shall be ignored in determining future Product Values.

(E) Provided daily group sampling is in effect pursuant to the provisions of paragraph (b)(1) of this section, and provided further the Product Value is −1.65 or less (e.g., −1.66), the affected lot (if within the official establishment) and all subsequent lots of like product prepared by and still within the official establishment shall be U.S. retained and further evaluated under paragraph (c) of this section. Except for release of individual lot pursuant to paragraph (c)(1), subsequently produced lots of like product shall continue to be U.S. retained until discontinued pursuant to paragraph (c)(2) of this section.

(c) *Compliance procedure during product retention.* When a product lot is U.S. retained under the provisions of paragraph (b)(2) of this section, the Department shall collect three randomly selected samples from each such lot and analyze them individually for PFF content. The PFF content of the three samples shall be evaluated to determine disposition of the lot as provided in paragraph (c)(1) of this section and the action to be taken on subsequently produced lots of like product as provided in paragraph (c)(2) of this section.[3]

[3] If the processor does not wish to have the product evaluated in this manner, alternate

Continued

(1) A product lot which is U.S. retained under the provisions of paragraph (b)(2) of this section may be released for entry into commerce provided one of the following conditions is met:

(i) The average PFF content of the three samples randomly selected from the lot is equal to or greater than the applicable minimum PFF percentage required by § 319.104 or § 319.105. Further processing to remove moisture for the purpose of meeting this provision is permissible. In lieu of further analysis to determine the effects of such processing, each 0.37 percent weight reduction due to moisture loss resulting from the processing may be considered the equivalent of a 0.1 percent PFF gain.

(ii) The lot of the product is relabeled to conform to the provisions of § 319.104 or § 319.105, under the supervision of a program employee.

(iii) The lot is one that has been prepared subsequent to preparation of the lot which, under the provisions of paragraph (c)(2) of this section, resulted in discontinuance of U.S. retention of new lots of like product. Such lot may be released for entry into commerce prior to receipt of analytical results for which sampling has been conducted. Upon receipt of such results, they shall be subjected to the provisions of paragraphs (b)(2)(i) and (c)(2) of this section.

(2) The PFF content of three randomly selected samples from each U.S. retained lot shall be used to maintain the Product Value described in paragraph (c)(2)(ii). The manner and effect of such maintenance shall be as follows: (i) Find the average PFF content of the three samples.

(ii) Determine the difference between that average and the applicable minimum PFF percentage requirement of § 319.104 or § 319.105. The resulting figure shall be negative when the average of the sample results is less than the applicable minimum PFF percentage requirement and shall be positive when the average of the sample results is greater than the applicable minimum PFF requirements.

(iii) Divide the resulting figure by the standard deviation assigned to the product's Group in paragraph (b)(1)(ii) of this section, to find the standardized difference.

(iv) Use the lesser of 1.30 and the standardized difference as the Sample Value.

(v) Add the first Sample Value thus calculated to the latest Product Value calculated under the provisions of paragraph (c)(2)(ii) of this section to find the new Product Value. To find each succeeding Product Value, add the most recent Sample Value to the existing Product Value; provided, however, that in no event shall the Product Value exceed 1.15. When the addition of a Sample Value to an existing Product Value results in a figure greater than 1.15, the Product Value shall be 1.15 and all previous Sample Values shall be ignored in determining future Product Values.

(vi) New lots of like product shall continue to be retained pending disposition in accordance with paragraph (c)(1) of this section until, after 5 days of production, the Product Value is 0.00 or greater, and the PFF content of no individual sample from a U.S. retained lot is less than the Absolute Minimum PFF requirement specified in paragraph (b)(2)(i) of this section. Should an individual sample fail to meet its Absolute Minimum PFF requirement, the 5-day count shall begin anew.

(vii) When U.S. retention of new lots is discontinued under the above provisions, maintenance of the Product Value shall revert to the provisions of paragraph (b)(2)(ii) of this section.

(3) For purposes of this section, the plant owner or operator shall have the option of temporarily removing a product from its Product Group, provided product lots are being U.S. retained, as produced, and provided further that the average production rate of the product, over the 8-week period preceding the week in which the first U.S. retained lot was prepared, is not greater than 20 percent of the production rate of its Group. When a product is thus removed from its Group, analytical results of

sampling plans may be used provided such plans have been formulated by the processor and approved by the Administrator prior to evaluation by the three-sample criteria, and provided the analyses specified in such plans are performed at the expense of the processor.

product samples shall not cause daily sampling of the Group. When pursuant to paragraph (c)(2)(vi) of this section, new lots of the product are no longer being U.S. retained, the product shall again be considered with its Group.

(d) *Adulterated and misbranded products.* Products not meeting specified PFF requirements, determined according to procedures set forth in this section, may be deemed adulterated under section 1(m)(8) of the Act (21 U.S.C. 601(m)(8)) and misbranded under section 1(n) of the Act (21 U.S.C. 601(n)).

(e) *Quality control.* Cured pork products bearing on their labeling the statement ''X% of Weight is Added Ingredients'' shall be prepared only under a quality control system or program in accordance with §318.4 of this subchapter. With respect to any other cured pork product, official establishments may institute quality control procedures under §318.4 of this subchapter. Cured pork products produced in such establishments may be exempt from the requirements of this section, provided in plant quality control procedures are shown to attain the same or higher degree of compliance as the procedures set forth in this section; provided, however, that all cured pork products produced shall be subject to the applicable Absolute Minimum PFF content requirement, regardless of any quality control procedures in effect.

[49 FR 14877, Apr. 13, 1984; 49 FR 33434, Aug. 23, 1984, as amended at 59 FR 33642, June 30, 1994; 60 FR 10304, Feb. 24, 1995; 62 FR 45025, Aug. 25, 1997]

§318.20 Use of animal drugs.

Animal drug residues are permitted in meat and meat food products if such residues are from drugs which have been approved by the Food and Drug Administration and any such drug residues are within tolerance levels approved by the Food and Drug Administration, unless otherwise determined by the Administrator and listed herein.

[50 FR 32165, Aug. 9, 1985]

§318.21 [Reserved]

§318.22 Determination of added water in cooked sausages.

(a) For purposes of this section, the following definitions apply.

(1) *Cooked sausage.* Cooked sausage is any product described in §319.140 and §§319.180–319.182 of this chapter.

(2) *Group 1 Protein-Contributing Ingredients.* Ingredients of livestock or poultry origin from muscle tissue which is skeletal or which is found in the edible organs, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing; meat byproducts; mechanically separated (species); and poultry products; except those ingredients processed by hydrolysis, extraction, concentrating or drying.

(3) *Group 2 Protein-Contributing Ingredients.* Ingredients from Gorup 1 protein-contributing ingredients processed by hydrolysis, extraction, concentrating, or drying, or any other ingredient which contributes protein.

(b) The amount of added water in cooked sausage is calculated by:

(1) Determining by laboratory analysis the total percentage of water contained in the cooked sausage; and

(2) Determining by laboratory analysis the total percentage of protein contained in the cooked sausage; and

(3) Calculating the percentage of protein in the cooked sausage contributed by the Group 2 protein-contributing ingredients; and

(4) Subtracting one pecent from the total percentage of protein calculated in (b)(3)); and

(5) Subtracting the remaining percentage of protein calculated in (b)(3) from the total protein content determined in (b)(2); and

(6) Calculating the percentage of indigenous water in the cooked sausage by multiplying the percentage of protein determined in (b)(5) by 4, (This amount is the percentage of water attributable to Group 1 protein-contributing ingredients and one percent of Group 2 protein-contributing ingredients in a cooked sausage.); and

(7) Subtracting the percentage of water calculated in (b)(6) from the total percentage of water determined

in (b)(1). (This amount is the percentage of added water in a cooked sausage.)[1]

[55 FR 7299, Mar. 1, 1990]

§ 318.23 Heat-processing and stabilization requirements for uncured meat patties.

(a) *Definitions.* For purposes of this section, the following definitions shall apply:

(1) *Patty.* A shaped and formed, comminuted, flattened cake of meat food product.

(2) *Comminuted.* A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.

(3) *Partially-cooked patties.* Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(4) *Char-marked patties.* Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(b) *Heat-processing procedures for fully-cooked patties.* (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

PERMITTED HEAT-PROCESSING TEMPERATURE/TIME COMBINATIONS FOR FULLY-COOKED PATTIES

Minimum internal temperature at the center of each patty (Degrees)		Minimum holding time after required internal temperature is reached (Time)	
Fahrenheit	Or centigrade	Minutes	Or seconds
151	66.1	.68	41
152	66.7	.54	32
153	67.2	.43	26
154	67.8	.34	20
155	68.3	.27	16
156	68.9	.22	13
157 (and up)	69.4 (and up)	.17	10

(2) The official establishment shall measure the holding time and temperature of at least one fully-cooked patty from each production line each hour of production to assure control of the heat process. The temperature measuring device shall be accurate within 1 degree F.

(3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.

(ii) In addition, in the case of a heating deviation, the official establishment may reprocess the affected product, using one of the methods in paragraph (b)(1) in this section; use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (b)(1) in this section, provided this does not violate the final product's standard of composition, upset the order of predominance of ingredients, or perceptibly affect the normal product characteristics; or relabel the affected product as a partially-cooked patty product, if it meets the stabilization requirements in paragraph (c) of this section.

(c) *Stabilization.* (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1

[1] The equation for the narrative description of the calculation for added water is as follows: AW = TW-(TP-(P-1.0))4, Where AW = Added Water, TW-Total Water Determined by Laboratory Analysis, TP = Total Protein Determined by Laboratory Analysis, P = Protein Contributed by Group 2 Protein-Contributing Ingredients, 1.0 = Percent Allowance for Group 2 Protein-Contributing Ingredients, 4 = Moisture-Protein Ratio for Cooked Sausage.

$\log_{10}$ multiplication of *Clostridium perfringens*, within the product.

(2) For each meat patty product produced using a stabilization process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(3) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(4) Partially cooked patties must bear the labeling statement ''Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F.).'' The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(5) Char-marked patties must bear the labeling statement ''Uncooked, Char-marked: For Safety, Cook Until Well Done (Internal Meat Temperature 160 degrees F.).'' The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

[64 FR 744, Jan. 6, 1999]

§ 318.24 Product prepared using advanced meat/bone separation machinery; process control.

(a) *General.* Meat, as defined in § 301.2 of this subchapter, may be derived by mechanically separating skeletal muscle tissue from the bones of livestock, other than skulls or vertebral column bones of cattle 30 months of age and older as provided in § 310.22 of this subchapter, using advances in mechanical meat/bone separation machinery (*i.e.*, AMR systems) that, in accordance with this section, recover meat—

(1) Without significant incorporation of bone solids or bone marrow as measured by the presence of calcium and iron in excess of the requirements in this section, and

(2) Without the presence of any brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

(b) *Process control.* As a prerequisite to labeling or using product as meat derived by the mechanical separation of skeletal muscle tissue from livestock bones, the operator of an establishment must develop, implement, and maintain procedures that ensure that the establishment's production process is in control.

(1) The production process is not in control if the skulls entering the AMR system contain any brain or trigeminal ganglia tissue, if the vertebral column bones entering the AMR system contain any spinal cord, if the recovered product fails otherwise under any provision of paragraph (c)(1), if the product is not properly labeled under the provisions of paragraph (c)(2), or if the spent bone materials are not properly handled under the provisions of paragraph (c)(3) of this section.

(2) The establishment must document its production process controls in writing. The program must be designed to ensure the on-going effectiveness of the process controls. If the establishment processes cattle, the program must be in its HACCP plan, its Sanitation SOP, or other prerequisite program. The program shall describe the on-going verification activities that will be performed, including the observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord; the testing of the product exiting the AMR system for bone solids, bone

marrow, spinal cord, and DRG as prescribed in paragraph (c)(1) of this section; the use of the product and spent bone materials exiting the AMR system; and the frequency with which these activities will be performed.

(3) The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process.

(4) The establishment shall make available to inspection program personnel the documentation described in paragraphs (b)(2) and (b)(3) of this section and any other data generated using these procedures.

(c) *Noncomplying product.* (1) Notwithstanding any other provision of this section, product that is recovered using advanced meat/bone separation machinery is not meat under any one or more of the following circumstances:

(i) *Bone solids.* The product's calcium content, measured by individual samples and rounded to the nearest 10th, is more than 130.0 mg per 100 g.

(ii) *Bone marrow.* The product's added iron content, measured by duplicate analyses on individual samples and rounded to the nearest 10th, is more than 3.5 mg per 100 g.[1]

(iii) *Brain or trigeminal ganglia.* Skulls that enter the AMR system have tissues of brain or trigeminal ganglia.

(iv) *Spinal cord.* Vertebral column bones that enter the AMR system have tissues of spinal cord, or the product that exits the AMR system contains spinal cord.

(v) *DRG.* The product that exits the AMR system contains DRG.

(2) If product that may not be labeled or used as ''meat'' under this section meets the requirements of § 319.5 of this subchapter, it may bear the name ''Mechanically Separated (Species)'' except as follows:

(i) If skulls or vertebral column bones of cattle younger than 30 months of age that enter the AMR system have tissues of brain, trigeminal ganglia, or spinal cord, the product that exits the AMR system shall not be used as an ingredient of a meat food product.

(ii) If product that exits the AMR system contains spinal cord or DRG from bones of cattle younger than 30 months of age, it shall not be used as an ingredient of a meat food product.

(iii) If product derived from any bones of cattle of any age does not comply with (c)(1)(i) or (ii), it may bear a common or usual name that is not false or misleading, except that the product may not bear the name ''Mechanically Separated (Beef).''

(3) Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system shall not be used as an ingredient of a meat food product.

[69 FR 1884, Jan. 12, 2004]

Subparts B–G [Reserved]

[1] The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100 g measured and rounded to the nearest 100th or more for that sample, minus the product of three factors: (1) The iron to protein ratio (IPR) factor associated with corresponding hand-deboned product; (2) the obtained protein (P) result (%) for that sample; and (3) a constant factor of 1.10. In formula, this can be written as: ExcFe = mFe − IPR × Protein × 1.10, where ExcFe represents the excess iron, expressed in units of mg/100 g; mFe represents the measured level of iron (Fe, mg/100 g), IPR is the iron to protein ratio for the appropriate hand-deboned product, and ''Protein'' is the measured level of protein rounded to the nearest 100th and expressed as a percentage of the total weight of the sample. In lieu of data demonstrating otherwise, the values of IPR to be used in the above formula are as follows: For beef products the value of IPR is equal to 0.104, except for any combination of bones that include any beef neckbone product, for which the value of 0.138 is to be used; for pork product, the IPR value is 0.052. Other IPR values can be used provided that the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the AMR system, based on analyses of hand-deboned samples, and the documented value is to be substituted for the IPR value (as applicable) in the above formula with respect to product that the establishment mechanically separates from those bones.

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

Subpart A—General

Subpart B—Raw Meat Products

Subpart C—Cooked Meats

Subpart D—Cured Meats, Unsmoked and Smoked

Subpart E—Sausage Generally: Fresh Sausage

Subpart F—Uncooked, Smoked Sausage

Subpart G—Cooked Sausage

Subpart H [Reserved]

Subpart I—Semi-Dry Fermented Sausage [Reserved]

Subpart J—Dry Fermented Sausage [Reserved]

Subpart K—Luncheon Meat, Loaves and Jellied Products

Subpart L—Meat Specialties, Puddings and Nonspecific Loaves

Subpart M—Canned, Frozen, or Dehydrated Meat Food Products

Subpart N—Meat Food Entree Products, Pies, and Turnovers

Subpart O—Meat Snacks, Hors d'Oeuvres, Pizza, and Specialty Items

Subpart P—Fats, Oils, Shortenings

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15597, Oct. 3, 1970, unless otherwise noted.

Subpart A—General

§ 319.1 Labeling and preparation of standardized products.

(a) Labels for products for which standards of identity or composition are prescribed in this part shall show the appropriate product name, an ingredient statement, and other label information in accordance with the special provisions, if any, in this part, and otherwise in accordance with the general labeling provisions in part 317 of this subchapter, and such products shall be prepared in accordance with the special provisions, if any, in this part and otherwise in accordance with the general provisions in this subchapter. Any product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products insofar as specific ingredients or procedures are not prescribed or prohibited by the provisions of this subchapter.

(b) Any binder or antimicrobial agent that has been found to be safe and suitable by the Food and Drug Administration and the Food Safety and Inspection Service may be used in the production of meat products with standards of identity in this part, where the product standards and applicable Federal regulations already permit the use of these types of ingredients.

[35 FR 15597, Oct. 3, 1970, as amended at 68 FR 22578, Apr. 29, 2003]

§ 319.2 Products and nitrates and nitrites.

Any product, such as frankfurters and corned beef, for which there is a standard in this part and to which nitrate or nitrite is permitted or required to be added, may be prepared without nitrate or nitrite and labeled with such standard name when immediately preceded with the term ''Uncured'' in the same size and style of lettering as the rest of such standard name: *Provided,* That the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate and nitrite: *And provided further,* That labeling for such product complies with the provisions of § 317.17(c) of this subchapter.

[44 FR 48961, Aug. 21, 1979]

§ 319.5 Mechanically Separated (Species).

(a) Mechanically Separated (Species) is any finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses and meeting the other provisions of this paragraph. Examples of such product are ''Mechanically Separated Beef'', ''Mechanically Separated Veal'', ''Mechanically Separated Pork'', and ''Mechanically Separated Lamb''. At least 98 percent of the bone particles present in such product shall have a maximum size no greater than 0.5 millimeter in their greatest dimension and there shall be no bone particles larger than 0.85 millimeter in their greatest dimension. The product resulting from the separating process shall not have a calcium content exceeding 0.75 percent, as a measure of a bone solids content of not more than 3 percent, and shall have a minimum PER of 2.5 (except as modified in paragraph (e)(1) of this section). Such product also shall have a protein content of not less than 14 percent and

a fat content of not more than 30 percent, or it shall be deemed to be product for processing. Such product failing to meet the bone particle size, calcium, or PER requirements of this paragraph shall only be used in producing animal fats. Where such product meets the bone particle size, calcium, and PER requirements of this paragraph, it may also be used in the formulation of meat food products in accordance with § 319.6.

(b) Mechanically Separated (Beef) is inedible and prohibited for use as human food.

(c)–(d) [Reserved]

(e)(1) An essential amino acid content of at least 33 percent of the total amino acids presents in ''Mechanically Separated (Species)'' shall be accepted as evidence of compliance with the protein quality requirement set forth in paragraph (a) of this section. For purposes of this paragraph, essential amino acid content includes isoleucine, leucine, lysine, methionine, phenylalanine, threonine, and valine content, and the total amino acids present include isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine, tyrosine, arginine, histidine, alanine, aspartic acid, glutamic acid, glycine, proline, serine, and hydroxyproline content.

(2) Analytical methods used by establishments in verifying the fat, protein, and calcium content of product consisting of or containing Mechanically Separated (Species) shall be among those listed in ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC),'' 16th edition, 1995, §§ 960.39, 976.21, 928.08 (Chapter 39), and 940.33 (Chapter 45), which is incorporated by reference, or, if no AOAC method is available, in the ''Chemistry Laboratory Guidebook,'' U.S. Department of Agriculture, Washington, D.C., March 1986 edition, sections 6.011–6.013, Revised June 1987 (pages 6–35 through 6–65), or by appropriate methods validated by scientific bodies in collaborative trials. The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' Chapter 39 and Chapter 45, subsection 45.2.06 (AOAC Official Method 940.33), 16th edition, 1995, are incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

[47 FR 28256, June 29, 1982, as amended at 54 FR 40631, Oct. 3, 1989; 59 FR 33642, June 30, 1994; 62 FR 45026, Aug. 25, 1997; 65 FR 34389, May 30, 2000; 69 FR 1874, Jan. 12, 2004]

§ 319.6 Limitations with respect to use of Mechanically Separated (Species).

(a) Meat food products required to be prepared from one species shall not contain Mechanically Separated (Species) of any other species.

(b) Mechanically Separated (Species) described in § 319.5 that has a protein content of not less than 14 percent and a fat content of not more than 30 percent may constitute up to 20 percent of the livestock and poultry product portion of any meat food product except those listed in paragraph (d) of this section.

(c) Mechanically Separated (Species) for processing described in § 319.5 may constitute up to 20 percent of the livestock and poultry product portion of any meat food product that is subject to a definition and standard of identity or composition in part 319 which establishes a maximum limit on the fat content of such meat food product except those listed in paragraph (d) of this section.

(d) Mechanically Separated (Species) and Mechanically Separated (Species) for processing described in § 319.5 shall not be used in baby, junior, or toddler foods, ground beef, hamburger, fabricated steaks (§ 319.15 (a), (b), and (d)), barbecued meats (§ 319.80), roast beef-parboiled and steam roasted (§ 319.81), corned (cured) beef cuts (§§ 319.100–319.103), certain cured pork products (§§ 319.104 (a)–(e) and 319.106), tripe with milk (§ 319.308), lima beans with ham and similar products (§ 319.310), beef with gravy and gravy with beef (§ 319.313), and meat pies (§ 319.500).

[47 FR 28257, June 29, 1982]

§ 319.10 Requirements for substitute standardized meat food products named by use of an expressed nutrient content claim and a standardized term.

(a) *Description.* The meat food products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 317.313(d), for a standardized product defined in this part and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in part 317, subpart B, of this subchapter. The expressed nutrient content claim shall comply with the requirements of § 317.313 of this subchapter and with the requirements of part 317, subpart B, of this subchapter which define the particular nutrient content claim that is used. The meat food product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the meat food product shall be similar to those of the standardized meat food product produced under this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in this part, the label shall include a statement in accordance with § 317.313(d)(1) and (2) of this subchapter that informs the consumer of such differences (*e.g.*, if appropriate, ''not recommended for frozen storage'' or ''not suitable for roller grilling''). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients used in substitute products.* (1) Ingredients used in the product shall be those ingredients provided for in the standard as defined in this part, except that safe and suitable ingredients permitted for use in meat food products as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in this part for which it is a substitute.

(2) An ingredient that is specifically required by the standard prescribed in this part shall not be replaced or exchanged with a similar ingredient from another source, for example, turnip chunks shall not replace potatoes in corned beef hash.

(3) An ingredient that is specifically prohibited from use in any meat food product by this part shall not be added to the substitute meat food product under this section.

(4) Unless otherwise specified in this part, a substitute meat food product must meet all other requirements of the applicable standards of identity or composition.

(5) Water and fat-replacers (*e.g.*, binders), in combination, may be added to replace fat in accordance with paragraph (c) of this section.

(6) Textured vegetable protein may be used by itself or in combination with other binders and water as a fat replacer in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute meat food product that complies with all parts of this section is the appropriate expressed nutrient content claim and the applicable standardized term.

(e) *Label declaration.* (1) Each of the ingredients used in the substitute meat food product shall be declared on the label as required by this section and part 317 of this subchapter.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in this part, shall be identified as such with an asterisk in the ingredients statement. The statement ''*Ingredients not in regular _____'' (the blank shall be filled in with the name of the traditional standardized product) or ''**Ingredients in excess of

amounts permitted in regular _____'' (the blank shall be filled in with the name of the traditional standardized product), or both, as appropriate, shall immediately follow the ingredients statement in the same type and size.

[70 FR 33818, June 10, 2005]

Subpart B—Raw Meat Products

§ 319.15 Miscellaneous beef products.

(a) *Chopped beef, ground beef.* ''Chopped Beef'' or ''Ground Beef'' shall consist of chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25 percent; and if in excess of natural proportions, its presence shall be declared on the label, in the ingredient statement required by § 317.2 of this subchapter, if any, and otherwise contiguous to the name of the product.

(b) *Hamburger.* ''Hamburger'' shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger only in accordance with the conditions prescribed in paragraph (a) of this section.

(c) *Beef patties.* ''Beef Patties'' shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings. Binders or extenders, Mechanically Separated (Species) used in accordance with § 319.6, and/or partially defatted beef fatty tissue may be used without added water or with added water only in amounts such that the product characteristics are essentially that of a meat pattie.

(d) *Fabricated steak.* Fabricated beef steaks, veal steaks, beef and veal steaks, or veal and beef steaks, and similar products, such as those labeled ''Beef Steak, Chopped, Shaped, Frozen,'' ''Minute Steak, Formed, Wafer Sliced, Frozen,'' ''Veal Steaks, Beef Added, Chopped—Molded—Cubed—Frozen, Hydrolyzed Plant Protein, and Flavoring'' shall be prepared by comminuting and forming the product from fresh and/or frozen meat, with or without added fat, of the species indicated on the label. Such products shall not contain more than 30 percent fat and shall not contain added water or extenders. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of fabricated beef steaks only in accordance with the conditions prescribed in paragraph (a) of this section.

(e) *Partially defatted beef fatty tissue.* ''Partially Defatted Beef Fatty Tissue'' is a beef byproduct derived from the low temperature rendering (not exceeding 120 °F.) of fresh beef fatty tissue. Such product shall have a pinkish color and a fresh odor and appearance.

[35 FR 15597, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 43 FR 26424, June 20, 1978; 47 FR 10784, Mar. 12, 1982; 47 FR 28257, June 29, 1982; 66 FR 54916, Oct. 31, 2001]

§ 319.29 Miscellaneous pork products.

(a) *Partially defatted pork fatty tissue.* ''Partially Defatted Pork Fatty Tissue'' is a pork byproduct derived from the low temperature rendering (not exceeding 120 °F.) of fresh pork fatty tissue, exclusive of skin. Such product shall have a pinkish color and a fresh odor and appearance.

Subpart C—Cooked Meats

§ 319.80 Barbecued meats.

Barbecued meats, such as product labeled ''Beef Barbecue'' or ''Barbecued Pork,'' shall be cooked by the direct action of dry heat resulting from the burning of hard wood or the hot coals therefrom for a sufficient period to assume the usual characteristics of a barbecued article, which include the formation of a brown crust on the surface and the rendering of surface fat. The product may be basted with a sauce during the cooking process. The weight of barbecued meat shall not exceed 70 percent of the weight of the fresh uncooked meat.

§ 319.81 Roast beef parboiled and steam roasted.

''Roast Beef Parboiled and Steam Roasted'' shall be prepared so that the weight of the finished product, excluding salt and flavoring material, shall not exceed 70 percent of the fresh beef weight. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder in such product. Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap may be used individually or collectively to the extent of 5 percent of the meat ingredients in the preparation of canned product labeled ''Roast Beef Parboiled and Steam Roasted.'' When beef cheek meat, beef head meat, or beef heart meat is used in the preparation of this product, its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter.

[35 FR 15597, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 66 FR 54916, Oct. 31, 2001]

Subpart D—Cured Meats, Unsmoked and Smoked

§ 319.100 Corned beef.

''Corned Beef'' shall be prepared from beef briskets, navels, clods, middle ribs, rounds, rumps, or similar cuts using one or a combination of the curing ingredients specified in a regulation permitting that use in this subchapter or 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B. Canned product labeled ''Corned Beef'' shall be prepared so that the weight of the finished product, excluding cure, salt, and flavoring material, shall not exceed 70 percent of the fresh beef weight. Corned beef other than canned shall be cured in pieces weighing not less than 1 pound, and if cooked, its weight shall not exceed the weight of the fresh uncured beef. Beef cheek meat, beef head meat and beef heart meat may be used to the extent of 5 percent of the meat ingredient in preparation of this product when trimmed as specified in § 319.81. When beef cheek meat, beef head meat, or beef heart meat is used in preparation of this product, its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter. The application of curing solution to beef cuts, other than briskets, which are intended for bulk corned beef shall not result in an increase in the weight of the finished cured product of more than 10 percent over the weight of the fresh uncured meat.

[35 FR 15597, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 38 FR 29215, Oct. 23, 1973; 64 FR 72174, Dec. 23, 1999]

§ 319.101 Corned beef brisket.

In preparing ''Corned Beef Brisket,'' the application of curing solution to the beef brisket shall not result in an increase in the weight of the finished cured product of more than 20 percent over the weight of the fresh uncured brisket. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured brisket.

§ 319.102 Corned beef round and other corned beef cuts.

In preparing ''Corned Beef Round'' and other corned beef cuts, except ''Corned Beef Briskets,'' the curing solution shall be applied to pieces of beef weighing not less than one pound and such application shall not result in an increased weight of the cured beef product of more than 10 percent over the weight of the fresh uncured beef cut. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured beef cut.

§ 319.103 Cured beef tongue.

In preparing ''Cured Beef Tongue,'' the application of curing solution to the fresh beef tongue shall not result in an increase in the weight of the cured beef tongue of more than 10 percent over the weight of the fresh uncured beef tongue.

§ 319.104 Cured pork products.

(a) Cured pork products, including hams, shoulders, picnics, butts and loins, shall comply with the minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

Type of cured pork product	Minimum meat PFF percentage [1]	Product name and qualifying statements
Cooked ham, loin [2].	20.5	(Common and usual).
	18.5	(Common and usual) with natural juices.
	17.0	(Common and usual) water added.
	<17.0	(Common and usual) and water product—X% of weight is added ingredients. [3]
Cooked shoulder, butt, picnic [2].	20.0	(Common and usual).
	18.0	(Common and usual) with natural juices.
	16.5	(Common and usual) water added.
	<16.5	(Common and usual) and water product—X% of weight is added ingredients. [3]
Uncooked cured ham, loin.	18.0	Uncooked (common and usual).
	<18.0	Uncooked (common and usual) and water product—X% of weight is added ingredients. [3]
Uncooked cured shoulder, butt, picnic.	17.5	Uncooked (common and usual).
	<17.5	Uncooked (common and usual) and water product—X% of weight is added ingredients. [3]

[1] The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw unprocessed pork expressed as a percent of the non-fat portion of the finished product; and compliance shall be determined under § 318.19 of this subchapter for domestic cured pork product and § 327.23 of this subchapter for imported cured pork product.

[2] The term ''cooked'' is not appropriate for use on labels of cured pork products heated only for the purpose of destruction of possible live trichinae.

[3] Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product—20% of Weight is Added Ingredients.

(b) Cured pork products for which there is a qualifying statement required in paragraph (a) of this section shall bear that statement as part of the product name in lettering not less than ⅜ inch in height, or in lettering not less than one-third the size of the largest letter in the product name if it is in the same color and style of print and on the same color background as the product name. However, the Administrator may approve smaller lettering for labeling of packages of 1 pound or less, provided such lettering is at least one-third the size and of the same color and style as the product name.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter.

(d) The binders provided for use in cured pork products in a regulation in this subchapter, in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B, may be used singly in those cured pork products labeled as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices.'' In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders and may be used singly in those cured pork products labeled as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices'': pork collagen at up to 3.5% of the product formulation. Unless their use is provided for in a regulation in this subchapter, in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B, or in this paragraph, these binders are not permitted to be used in combination with another such binder listed for use in cured pork products. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

[49 FR 14879, Apr. 13, 1984, as amended at 50 FR 9792, Mar. 12, 1985; 53 FR 5151, Feb. 22, 1988; 57 FR 42888, Sept. 17, 1992; 62 FR 45026, Aug. 25, 1997; 63 FR 148, Jan. 5, 1998; 64 FR 27904, May 24, 1999; 65 FR 34389, May 30, 2000; 66 FR 54916, Oct. 31, 2001]

§ 319.105 "Ham patties," "Chopped ham," "Pressed ham," "Spiced ham," and similar products.

(a) Finely divided (chopped, ground, flaked, chipped) cured ham products such as ''Ham patties,'' ''Chopped ham,'' ''Pressed ham,'' and ''Spiced ham'' shall comply with minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

Type of cured pork product	Minimum meat PFF percentage [1]	Product name and qualifying statements
"Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham"	19.5	(Common and usual).
"Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham"	17.5	(Common and usual) with natural juices.
"Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham"	16.0	(Common and usual) water added.
"Ham Patties," "Chopped Ham," "Pressed Ham," and "Spiced Ham"	<16.0	(Common and usual) and water product—(x)% of weight is added ingredients. [2]

[1] The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw, unprocessed pork expressed as a percent of the nonfat portion of the finished product; and compliance shall be determined under section 318.19 of this subchapter.

[2] Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product—20% of Weight is Added Ingredients.

(b) Cured pork products prepared under this section except ''Ham patties'' may contain finely chopped ham shank meat to the extent of 25 percent over that normally present in boneless ham. Mechanically Separated (Species) Product may be used in accordance with § 319.6.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter, and those cured pork products prepared under this section for which there is a qualifying statement required shall comply with the requirements of § 319.104(b) of this subchapter.

(d) In addition to the other requirements of this section, ''Ham Patties'' may not contain more than 35 percent fat, by analysis.

[49 FR 14880, Apr. 13, 1984, as amended at 53 FR 5151, Feb. 22, 1988; 62 FR 45026, Aug. 25, 1997; 65 FR 34389, May 30, 2000]

§ 319.106 "Country Ham," "Country Style Ham," "Dry Cured Ham," "Country Pork Shoulder," "Country Style Pork Shoulder," and "Dry Cured Pork Shoulder."

(a) ''Country Ham,'' ''Country Style Ham,'' or ''Dry Cured Ham,'' and ''Country Pork Shoulder,'' ''Country Style Pork Shoulder,'' or ''Dry Cured Pork Shoulder.'' are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of ''ham,'' as specified in § 317.8(b)(13) of this subchapter, or from a single piece of meat from a pork shoulder. They are prepared in accordance with paragraph (c) of this section by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients as specified in paragraph (d) of this section. They may not be injected with curing solutions nor placed in curing solutions.

(b)(1) The entire exterior of the ham or pork shoulder shall be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.

(2) Additional salt, or salt mixed with other permitted ingredients, may be reapplied to the product as necessary to insure complete penetration.

(3) When sodium or potassium nitrate, or sodium or potassium nitrite, or a combination thereof, is used, the application of salt shall be in sufficient quantity to insure that the finished product has an internal salt content of at least 4 percent.

(4) When no sodium nitrate, potassium nitrate, sodium nitrite, potassium nitrite or a combination thereof is used, the application of salt shall be in sufficient quantity to insure that the finished product has a brine concentration of not less than 10 percent or a water activity of not more than 0.92.

(5) [Reserved]

(6) [Reserved]

(7) The weight of the finished hams and pork shoulders covered in this section shall be at least 18 percent less than the fresh uncured weight of the article.

(c) The optional ingredients for products covered in this section are:

(1) Nutritive sweeteners, spices, seasonings and flavorings.

(2) Sodium or potassium nitrate and sodium or potassium nitrite if used as prescribed in this section and in accordance with a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

[42 FR 3299, Jan. 18, 1977, as amended at 64 FR 72174, Dec. 23, 1999; 83 FR 25307, May 31, 2018]

§ 319.107 Bacon.

The weight of cured pork bellies ready for slicing and labeling as ''Bacon'' shall not exceed the weight of the fresh uncured pork bellies.

[49 FR 14880, Apr. 13, 1984]

Subpart E—Sausage Generally: Fresh Sausage

§ 319.140 Sausage.

Except as otherwise provided in this section, or under the Poultry Products Inspection Act with respect to products consisting partly of poultry, sausage is the coarse or finely comminuted meat food product prepared from one or more kinds of meat or meat and meat byproducts, containing various amounts of water as provided for elsewhere in this part, and usually seasoned with condimented proportions of condimental substances, and frequently cured. Certain sausage as provided for elsewhere in this part may contain binders and extenders as provided in a regulation permitting that use in this subchapter or in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B. In addition to the binders and extenders referred to in the preceding sentence, the following two substances may also be used as binders in those sausages in which the use of such class of substances is permitted: pork collagen at up to 3.5% of the product formulation and transglutaminase enzyme at up to 65 ppm of the product formulation. Sausage may not contain phosphates except that phosphates listed in a regulation permitting that use in this subchapter or in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B may be used in cooked sausage. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of sausage which is not cooked in an amount not to exceed 3 percent of the total ingredients in the formula. Cooked sausages such as Polish sausage, cotto salami, braunschweiger, liver sausage, and similar cooked sausage products may contain no more than 10 percent of added water in the finished product. Sausage may contain Mechanically Separated (Species) used in accordance with § 319.6.

[55 FR 34683, Aug. 24, 1990, as amended at 64 FR 72175, Dec. 23, 1999; 66 FR 54916, Oct. 31, 2001]

§ 319.141 Fresh pork sausage.

''Fresh Pork Sausage'' is sausage prepared with fresh pork or frozen pork or both, but not including pork byproducts, and may contain Mechanically Separated (Species) in accordance with § 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

§ 319.142 Fresh beef sausage.

''Fresh Beef Sausage'' is sausage prepared with fresh beef or frozen beef, or both, but not including beef byproducts, and may contain Mechanically Separated (Species) used in accordance with § 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 30 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.143 Breakfast sausage.

''Breakfast sausage'' is sausage prepared with fresh and/or frozen meat; or fresh and/or frozen meat and meat byproducts, and may contain Mechanically Separated (Species) in accordance with § 319.6, and may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used. Binders or extenders may be added as provided in § 319.140 of this part.

[55 FR 34683, Aug. 24, 1990, as amended at 66 FR 54916, Oct. 31, 2001]

§ 319.144 Whole hog sausage.

''Whole Hog Sausage'' is sausage prepared with fresh and/or frozen meat from swine in such proportions as are normal to a single animal, and may include any Mechanically Separated (Species) produced from the animal and used in accordance with § 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

§ 319.145 Italian sausage products.

(a) Italian sausage products are cured or uncured sausages containing at least 85 percent meat, or combination of meat and fat, with the total fat content constituting not more than 35 percent of the finished product. Such products shall be prepared in accordance with the provisions of paragraph (a) (1), (2) or (3) of this section, and shall contain salt, pepper, and either fennel or anise, or a combination of fennel and anise. Such products may contain any or all of the optional ingredients listed in paragraph (b) of this section.

(1) ''Italian Sausage'' shall be prepared with fresh or frozen pork, or pork and pork fat, and may contain Mechanically Separated (Species) in accordance with § 319.6.

(2) ''Italian Sausage with Beef,'' ''Italian Sausage with Veal,'' or ''Italian Sausage with Beef and Veal,'' shall be prepared so that fresh or frozen pork constitutes the major portion of the meat content requirement of this paragraph. Mechanically Separated (Species) may be used in accordance with § 319.6.

(3) ''Italian Beef Sausage'' or ''Kosher Italian Beef Sausage'' shall be prepared with fresh or frozen beef or beef and beef fat. ''Italian Veal Sausage'' or ''Kosher Italian Veal Sausage'' shall be prepared with fresh or frozen veal or veal and veal fat. Mechanically Separated (Species) may be used in accordance with § 319.6.

(4) Italian sausage products made in conformance with the provisions of paragraphs (a) (1), (2), and (3) of this section, and with paragraphs (b) and (c) of this section, may contain sodium nitrite or potassium nitrite in amounts not to exceed those allowed in a regulation permitting that use in this subchapter or in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B, provided that such products are labeled with the word ''cured'' in the product name, such as ''Cured Italian Sausage.'' The word ''cured'' shall be displayed on the product label in the same size and style of lettering as other words in the product name.

(b) Optional ingredients permitted in Italian sausage products include:

(1) Spices (including paprika) and flavorings.

(2) Water or ice to facilitate chopping or mixing, but not to exceed 3 percent of the total weight of all ingredients including the water.

(3) Red or green peppers, or both.

(4) Dehydrated or fresh onions, garlic, and parsley.

(5) Sugar, dextrose, corn syrup, corn syrup solids, and glucose syrup.

(6) Monosodium glutamate and antioxidants in accordance with the chart of substances a regulation permitting that use in this subchapter or in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B.

(c) If Italian sausage products are cooked or smoked, determination of compliance with the provisions of paragraphs (a) and (b) of this section shall be based on the uncooked or unsmoked product. The product before cooking or smoking shall contain no more than 3 percent water as specified in paragraph (b)(2) of this section. Product which is cooked shall be labeled with the word ''cooked'' in the product name, such as ''Cooked Italian Sausage'' or ''Cooked Cured Italian Sausage.'' Product which is smoked shall be labeled with the word ''smoked'' in the product name, such as ''Smoked Italian Sausage'' or ''Smoked Cured Italian Sausage.'' The words ''cooked'' and ''smoked'' shall be displayed on the product label in the same size and style of lettering as other words in the product name.

[41 FR 2630, Jan. 19, 1976, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982; 49 FR 46533, Nov. 27, 1984; 64 FR 72175, Dec. 23, 1999; 83 FR 25307, May 31, 2018]

Subpart F—Uncooked, Smoked Sausage

§ 319.160 Smoked pork sausage.

''Smoked Pork Sausage'' is pork sausage that is smoked with hardwood or other approved nonresinous materials. It may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water, or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 47 FR 28258, June 29, 1982]

Subpart G—Cooked Sausage

§ 319.180 Frankfurter, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products.

(a) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages are comminuted, semisolid sausages prepared from one or more kinds of raw skeletal muscle meat or raw skeletal muscle meat and raw or cooked poultry meat, and seasoned and cured, using one or more of the curing agents in accordance with a regulation permitting that use in this subchapter or in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B. They may or may not be smoked. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing or to dissolve the curing ingredients but the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. Such products may contain raw or cooked poultry meat and/or Mechanically Separated (Kind of Poultry) without skin and without kidneys and sex glands used in accordance with § 381.174, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and Mechanically Separated (Species) used in accordance with § 319.6. Such poultry meat ingredients shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of § 381.118 of this chapter.

(b) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages that are labeled with the phrase ''with byproducts'' or ''with variety meats'' in the product name are comminuted, semisolid sausages consisting of not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts, or not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts and raw or cooked poultry products; and seasoned and cured, using one or more of the curing ingredients in accordance with a regulation permitting that use in this subchapter or in 9 CFR chapter III, subchapter E, or in 21 CFR chapter I, subchapter A or subchapter B. They may or may not be smoked. Partially defatted pork fatty tissue or partially defatted beef fatty tissue, or a combination of both, may be used in an amount not exceeding 15 percent of the meat and meat byproducts or meat, meat byproducts, and poultry products ingredients. The finished products shall not contain more than 30 percent fat.

Water or ice, or both, may be used to facilitate chopping or mixing to dissolve the curing and seasoning ingredients, the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. These sausage products may contain poultry products and/or Mechanically Separated (Kind of Poultry) used in accordance with §381.174, individually or in combination, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and may contain Mechanically Separated (Species) used in accordance with §319.6. Such poultry products shall not contain kidneys or sex glands. The amount of poultry skin present in the sausage must not exceed the natural proportion of skin present on the whole carcass of the kind of poultry used in the sausage, as specified in §381.117(d) of this chapter. The poultry products used in the sausage shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of §381.118 of this chapter. Meat byproducts used in the sausage shall be designated individually in the ingredient statement on the label for such sausage in accordance with §317.2 of this chapter.

(c) A cooked sausage as defined in paragraph (a) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst. When such sausage products are prepared with meat from a single species of cattle, sheep, swine, or goats they shall be labeled with the term designating the particular species in conjunction with the generic name, e.g., ''Beef Frankfurter,'' and when such sausage products are prepared in part with Mechanically Separated (Species) in accordance with §319.6, they shall be labeled in accordance with §317.2(j)(13) of this subchapter.

(d) A cooked sausage as defined in paragraph (b) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst, in conjunction with the phrase ''with byproducts'' or ''with variety meats'' with such supplemental phrase shown in a prominent manner directly contiguous to the generic name and in the same color on an identical background.

(e) Binders and extenders as provided in §319.140 of this part may be used in cooked sausage that otherwise comply with paragraph (a) or (b) of this section. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

(f) Cooked sausages shall not be labeled with terms such as ''All Meat'' or ''All (Species),'' or otherwise to indicate they do not contain nonmeat ingredients or are prepared only from meat.

(g) For the purposes of this section: Poultry meat means deboned chicken meat or turkey meat, or both, without skin or added fat; poultry products mean chicken or turkey, or chicken meat or turkey meat as defined in §381.118 of this chapter, or poultry byproducts as defined in §381.1 of this chapter; and meat byproducts (or variety meats), mean pork stomachs or snouts; beef, veal, lamb, or goat tripe; beef, veal, lamb, goat, or pork hearts, tongues, fat, lips, weasands, and spleens; and partially defatted pork fatty tissue, or partially defatted beef fatty tissue.

[38 FR 14742, June 5, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §319.180, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 319.181 Cheesefurters and similar products.

''Cheesefurters'' and similar products are products in casings which resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article. They may contain binders and extenders as provided in §424.21(c) of subchapter E. Limits on use as provided in §424.21 are intended to be exclusive of the cheese constituent. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance. These products shall contain no more

than 40 percent of a combination of fat and added water, and no more than 30 percent fat and shall comply with the other provisions for cooked sausages that are in this subchapter.

[55 FR 34683, Aug. 24, 1990, as amended at 56 FR 41448, Aug. 21, 1991; 76 FR 82078, Dec. 30, 2011]

§ 319.182 Braunschweiger and liver sausage or liverwurst.

(a) ''Braunschweiger'' is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, and/or veal livers computed on the weight of the fresh livers. It may also contain pork and/or beef fat. Mechanically Separated (Species) may be used in accordance with §319.6. Binders and extenders may be used as permitted in §319.140. The product may have a smoked taste characteristic, which may be imparted by use of smoked meats, smoke flavoring or smoking. If prepared from components of a single species, the product name may reflect the species, e.g., ''Beef Braunschweiger.'' Braunschweiger may also be labeled as any of the following: ''Braunschweiger—A Liver Sausage,'' ''Braunschweiger—A Liverwurst,'' or ''Braunschweiger (Liver Sausage)'' or ''Braunschweiger (Liverwurst).''

(b) ''Liver Sausage'' or ''Liverwurst'' is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, veal, sheep, and/or goat livers computed on the weight of the fresh livers. It may also contain pork and/or beef byproducts. Mechanically Separated (Species) may be used in accordance with §319.6. Binders and extenders maybe used as permitted in §319.140. If prepared from components of a single species, the product name may reflect that species, e.g., ''Pork Liver Sausage.''

[47 FR 36108, Aug. 19, 1982]

Subpart H [Reserved]

Subpart I—Semi-Dry Fermented Sausage [Reserved]

Subpart J—Dry Fermented Sausage [Reserved]

Subpart K—Luncheon Meat, Loaves and Jellied Products

§ 319.260 Luncheon meat.

''Luncheon Meat'' is a cured, cooked meat food product made from comminuted meat. Mechanically Separated (Species) may be used in accordance with §319.6. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of luncheon meat in an amount not to exceed 3 percent of the total ingredients.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.261 Meat loaf.

''Meat Loaf'' is a cooked meat food product in loaf form made from comminuted meat. Mechanically Separated (Species) may be used in accordance with §319.6. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

Subpart L—Meat Specialties, Puddings and Nonspecific Loaves

§ 319.280 Scrapple.

''Scrapple'' shall contain not less than 40 percent meat and/or meat byproducts computed on the basis of the fresh weight, exclusive of bone. Mechanically Separated (Species) may be used in accordance with §319.6. The meal or flour used may be derived from grain and/or soybeans.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.281 Bockwurst.

(a) Bockwurst is an uncured, comminuted meat food product which may or may not be cooked. It contains meat, milk or water or a combination thereof, eggs, vegetables, and any of the optional ingredients listed in paragraph (b) of this section; and is prepared in accordance with the provisions of paragraphs (a)(1), (2), (3), and (4) of this section.

(1) Meat shall constitute not less than 70 percent of the total weight of

the product and shall consist of pork or a mixture of pork and veal, pork and beef, or pork, veal, and beef. Such meat shall be fresh or fresh frozen meat. Pork may be omitted when the specie or species of meat used in the product is identified in the product name (e.g., Veal Bockwurst, Beef Bockwurst, or Beef and Veal Bockwurst). Mechanically Separated (Species) may be used in accordance with § 319.6.

(2) The ''milk'' may be fresh whole milk, dried milk, nonfat dry milk, calcium reduced dried skim milk, enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate, or any combination thereof.

(3) ''Eggs'' refer to whole eggs that are fresh, frozen, or dried.

(4) ''Vegetables'' refer to onions, chives, parsley, and leeks, alone or in any combination.

(b) Bockwurst may contain one or more of the following optional ingredients:

(1) Pork fat.

(2) Celery, fresh or dehydrated.

(3) Spices, flavorings.

(4) Salt.

(5) Egg whites, fresh, frozen, or dried.

(6) Corn syrup solids, corn syrup, or glucose syrup with a maximum limit of 2 percent individually or collectively, calculated on a dry basis. The maximum quantities of such ingredients shall be computed on the basis of the total weight of the ingredients.

(7) Autolyzed yeast extract, hydrolyzed plant protein, milk protein hydrolysate, and monosodium glutamate.

(8) Sugars (sucrose and dextrose).

(9) Binders and extenders may be added as provided in § 424.21(c) of subchapter E. When any such substance is added to bockwurst, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance.

(c) If bockwurst is cooked or partially cooked, the composition of the raw mix from which it is prepared shall be used in determining whether it meets the requirements of this section.

[40 FR 18542, Apr. 29, 1975, as amended at 41 FR 18089, Apr. 30, 1976; 43 FR 26425, June 20, 1978; 45 FR 10318, Feb. 15, 1980; 47 FR 26374, June 18, 1982; 47 FR 28257, 28258, June 29, 1982; 55 FR 34683, Aug. 24, 1990; 56 FR 41448, Aug. 21, 1991; 76 FR 82078, Dec. 30, 2011]

Subpart M—Canned, Frozen, or Dehydrated Meat Food Products

§ 319.300 Chili con carne.

''Chili con carne'' shall contain not less than 40 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. Head meat, cheek meat, and heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients under specific declaration on the label. The mixture may contain binders and extenders as provided in § 424.21(c) of subchapter E.

[55 FR 34684, Aug. 24, 1990, as amended at 76 FR 82078, Dec. 30, 2011]

§ 319.301 Chili con carne with beans.

Chili con carne with beans shall contain not less than 25 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. Head meat, cheek meat, or heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients, and its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter. The mixture may contain binders and extenders as provided in § 424.21(c) of subchapter E.

[55 FR 34684, Aug. 24, 1990, as amended at 76 FR 82078, Dec. 30, 2011]

§ 319.302 Hash.

''Hash'' shall contain not less than 35 percent of meat computed on the weight of the cooked and trimmed meat. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the weight of the uncooked fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.303 Corned beef hash.

(a) ''Corned Beef Hash'' is the semi-solid food product in the form of a compact mass which is prepared with beef, potatoes, curing agents, seasonings, and any of the optional ingredients listed in paragraph (b) of this section, in accordance with the provisions of paragraphs (a) (1), (2), (3) and (4) of this section and the provisions of paragraph (c) of this section.

(1) Either fresh beef, cured beef, or canned corned beef or a mixture of two or more of these ingredients, may be used, and the finished product shall contain not less than 35 percent of beef computed on the weight of the cooked and trimmed beef. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the weight of the uncooked fresh meat.

(2) ''Potatoes'' refers to fresh potatoes, dehydrated potatoes, cooked dehydrated potatoes, or a mixture of two or more of these ingredients.

(3) The curing agents that may be used are salt, sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or a combination of two or more of these ingredients. When sodium nitrate, or sodium nitrite, potassium nitrate, or potassium nitrite is used it shall be used in amounts not exceeding those specified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

(4) The seasonings that may be used, singly or in combination, are salt, sugar (sucrose or dextrose), spice, and flavoring, including essential oils, oleoresins, and other spice extractives.

(b) Corned beef hash may contain one or more of the following optional ingredients:

(1) Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap, may be used individually or collectively to the extent of 5 percent of the meat ingredients;

(2) Onions, including fresh onions, dehydrated onions, or onion powder;

(3) Garlic, including fresh garlic, dehydrated garlic, or garlic powder;

(4) Water;

(5) Beef broth or beef stock;

(6) Monosodium glutamate;

(7) Hydrolyzed plant protein;

(8) Beef fat;

(9) Mechanically Separated (Species) when derived from carcasses of cattle may be used in accordance with § 319.6.

(c) The finished product shall not contain more than 15 percent fat nor more than 72 percent moisture.

(d)(1) When any ingredient specified in paragraph (b)(1) of this section is used, the label shall bear the following applicable statement: ''Beef cheek meat constitutes 5 percent of the meat ingredient,'' or ''Beef head meat constitutes 5 percent of the meat ingredient,'' or ''Beef heart meat constitutes 5 percent of the meat ingredient.'' When two or more of the ingredients are used, the words ''Constitutes 5 percent of meat ingredient'' need only appear once.

(2) Whenever the words ''corned beef hash'' are featured on the label so conspicuously as to identify the contents, the statements prescribed in paragraph (d)(1) of this section shall immediately and conspicuously precede or follow such name without intervening written, printed, or other graphic matter.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982; 64 FR 72175, Dec. 23, 1999]

§ 319.304 Meat stews.

Meat stews such as ''Beef Stew'' or ''Lamb Stew'' shall contain not less than 25 percent of meat of the species named on the label, computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.305 Tamales.

''Tamales'' shall be prepared with at least 25 percent meat computed on the weight of the uncooked fresh meat in relation to all ingredients of the tamales. When tamales are packed in sauce or gravy, the name of the product shall include a prominent reference to the sauce or gravy; for example, ''Tamales With Sauce'' or ''Tamales With Gravy.'' Product labeled ''Tamales With Sauce'' or ''Tamales With Gravy'' shall contain not less

than 20 percent meat, computed on the weight of the uncooked fresh meat in relation to the total ingredients making up the tamales and sauce or the tamales and gravy. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

§ 319.306 Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products.

''Spaghetti with Meatballs and Sauce'' and ''Spaghetti with Meat and Sauce,'' and similar products shall contain not less than 12 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. The presence of the sauce or gravy constituent shall be declared prominently on the label as part of the name of the product. Meatballs may be prepared with farinaceous material and with other binders and extenders as provided in § 424.21(c) of subchapter E.

[55 FR 34684, Aug. 24, 1990, as amended at 76 FR 82078, Dec. 30, 2011]

§ 319.307 Spaghetti sauce with meat.

''Spaghetti Sauce with Meat'' shall contain not less than 6 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.308 Tripe with milk.

''Tripe with Milk'' shall be prepared so that the finished canned article, exclusive of the cooked-out juices and milk, will contain at least 65 percent tripe. The product shall be prepared with not less than 10 percent milk.

§ 319.309 Beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products.

''Beans with Frankfurters in Sauce,'' ''Sauerkraut with Wieners and Juice,'' and similar products shall contain not less than 20 percent frankfurters or wieners computed on the weight of the smoked and cooked sausage prior to its inclusion with the beans or sauerkraut.

§ 319.310 Lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce, and similar products.

''Lima Beans with Ham in Sauce,'' ''Beans with Ham in Sauce,'' ''Beans with Bacon in Sauce,'' and similar products shall contain not less than 12 percent ham or bacon computed on the weight of the smoked ham or bacon prior to its inclusion with the beans and sauce.

§ 319.311 Chow mein vegetables with meat, and chop suey vegetables with meat.

''Chow Mein Vegetables with Meat'' and ''Chop Suey Vegetables with Meat'' shall contain not less than 12 percent meat computed on the weight of the uncooked fresh meat prior to its inclusion with the other ingredients. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.312 Pork with barbecue sauce and beef with barbecue sauce.

''Pork with Barbecue Sauce'' and ''Beef with Barbecue Sauce'' shall consist of not less than 50 percent cooked meat of the species specified on the label. Mechanically Separated (Pork) may be used in accordance with § 319.6.

[69 FR 34916, June 23, 2004]

§ 319.313 Beef with gravy and gravy with beef.

''Beef with Gravy'' and ''Gravy with Beef'' shall not be made with beef which, in the aggregate for each lot contains more than 30 percent trimmable fat, that is, fat which can be removed by thorough, practicable trimming and sorting.

Subpart N—Meat Food Entree Products, Pies, and Turnovers

§ 319.500 Meat pies.

Meat pies such as ''Beef Pie,'' ''Veal Pie,'' and ''Pork Pie'' shall contain meat of the species specified on the

label, in an amount not less than 25 percent of all ingredients including crust and shall be computed on the basis of the fresh uncooked meat.

Subpart O—Meat Snacks, Hors d'Oeuvres, Pizza, and Specialty Items

§ 319.600 [Reserved]

Subpart P—Fats, Oils, Shortenings

§ 319.700 Margarine or oleomargarine.[1]

(a) Margarine or oleomargarine is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed under § 938.06 (Chapter 33) of the ''Indirect Methods'' in ''Official Methods of Analysis of the Association of Official Analytical Chemists'', 15th edition, 1990.[2] The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is produced from one or more of the ingredients designated in paragraph (a)(1) of this section, and one or more of the ingredients designated in paragraph (a)(2) of this section, to which may be added one or more of the optional ingredients designated in paragraph (b) of this section. Margarine or oleomargarine contains Vitamin A as provided for in paragraph (a)(3) of this section.

(1) Edible fats and oils or mixtures of these, whose origin is vegetable or rendered animal fats from cattle, sheep, swine or goats.

(2)(i) Water; milk; milk products including, but not limited to, the liquid, condensed, or dry form of whey, reduced lactose whey, reduced minerals whey, or whey protein concentrate, non-lactose-containing whey components, casein, or caseinate; or other suitable edible protein, including albumin, vegetable proteins, or soy protein isolate; or any mixture of two or more of the articles designated in this subparagraph, in amounts not greater than reasonably required to accomplish the desired effect.

(ii) The articles designated in this subparagraph shall be pasteurized and then may be subjected to the action of harmless bacterial starters. One or more of the articles designated in this subparagraph is intimately mixed with the edible fat or oil ingredients, or both, to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine or oleomargarine contains not less than 15,000 International Units (IU) of ViTamin A per pound or 33,000 IU per kilogram.

(b)(1) Vitamin D in such quantity that the finished margarine or oleomargarine contains not less than 1,500 IU of Vitamin D per pound or 3,300 IU per kilogram.

(2) Salt (sodium chloride); or potassium chloride for dietary margarine or oleomargarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers identified in a regulation permitting that use in this subchapter or a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: Mono- and diglycerides of fatty acids esterified with any or all of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts, 0.5 percent; such mono- and diglycerides in combination with the sodium sulfoacetate derivatives thereof, 0.5 percent; polyglycerol esters of fatty acids, 0.5 percent; 1,2-propylene glycol esters of fatty acids, 2 percent; lecithin, 0.5 percent.

[1] Insofar as the standard contains provisions relating to margarine or oleomargarine which does not contain any meat food products, such provisions merely reflect the applicable standard under the Federal Food, Drug, and Cosmetic Act.

[2] A copy of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

(5) Preservatives identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: Sorbic acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Antioxidants identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: propyl, octyl and dodecyl gallates, BHT (butylated hydroxytoluene), BHA (butylated hydroxyanisole), ascorbyl palmitate, ascorbyl stearate, all individually or in combination, 0.02 percent. Instead of these antioxidants, TBHQ (tertiary butylhydroquinone), alone or in combination only with BHT and/or BHA, with a maximum 0.02 percent by weight of the fat and oil content.

(7) Coloring agents identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Parts 73, 74, 81, or 82, in amounts sufficient for purpose.[3] For the purpose of this subparagraph, provitamine A (beta-carotene) shall also be deemed to be a coloring agent.

(8) Flavoring substances in amounts sufficient for purpose.

(9) Acidulants identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, in amounts sufficient for purpose: adipic acid; citric and lactic acids and their potassium and sodium salts; phosphoric acid; L-tartaric acid and its sodium and sodium-potassium salts; and hydrochloric acid.

(10) Alkalizers identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, in amounts sufficient for purpose: potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium hydroxide.

(11) For the purposes of this section, the term ''milk'' unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word ''milk'' in the ingredient statement.

[48 FR 52697, Nov. 22, 1983, as amended at 50 FR 3739, Jan. 28, 1985; 54 FR 40632, Oct. 3, 1989; 59 FR 33642, June 30, 1994; 64 FR 72175, Dec. 23, 1999]

§ 319.701 Mixed fat shortening.

Shortening prepared with a mixture of meat fats and vegetable oils may be identified either as ''Shortening Prepared with Meat Fats and Vegetable Oils'' or ''Shortening Prepared with Vegetable Oils and Meat Fats'' depending on the predominance of the fat and oils used, or the product may be labeled ''Shortening'' when accompanied by an ingredient statement with ingredients listed in descending order of predominance.

§ 319.702 Lard, leaf lard.

(a) Lard is the fat rendered from clean and sound edible tissues from swine. The tissues may be fresh, frozen, cooked, or prepared by other processes approved by the Administrator in specific cases, upon his determination that the use of such processes will not result in the adulteration or misbranding of the lard. The tissues shall be reasonably free from blood, and shall not include stomachs, livers, spleens, kidneys, and brains, or settlings and skimmings. ''Leaf Lard'' is lard prepared from fresh leaf (abdominal) fat.

(b) Lard (when properly labeled) may be hardened by the use of lard stearin or hydrogenated lard or both and may contain refined lard and deodorized lard, but the labels of such lard shall state such facts, as applicable.

(c) Products labeled ''Lard'' or ''Leaf Lard'' must have the following identity

[3] Colored margarine or oleomargarine is also subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 347), as reflected in § 317.8(h)(24) of this subchapter.

and quality characteristics to insure good color, odor, and taste of finished product:

(1) Color	White when solid, Maximum 3.0 red units in a 5¼ inch cell on the Lovibond scale.
(2) Odor and taste	Characteristic and free from foreign odors and flavors.
(3) Free fatty acid	Maximum 0.5 percent (as oleic) or 1.0 acid value, as milligrams KOH per gram of sample.
(4) Peroxide value	Maximum 5.0 (as milliequivalents of peroxide per kilogram fat).
(5) Moisture and volatile matter.	Maximum 0.2 percent.
(6) Insoluble impurities	By appearance of liquid, fat or maximum 0.05 percent.

(d) Product found upon inspection not to have the characteristics specified in paragraph (c) of this section but found to be otherwise sound and in compliance with paragraph (a) of this section may be further processed for the purpose of achieving such characteristics.

[43 FR 25420, June 13, 1978]

§ 319.703 Rendered animal fat or mixture thereof.

''Rendered Animal Fat,'' or any mixture of fats containing edible rendered animal fat, shall contain no added water, except that ''Puff Pastry Shortening'' may contain not more than 10 percent of water.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 25420, June 13, 1978]

Subpart Q—Meat Soups, Soup Mixes, Broths, Stocks, Extracts

§ 319.720 Meat extract.

Meat extract (e.g., ''Beef Extract'') shall contain not more than 25 percent of moisture.

§ 319.721 Fluid extract of meat.

Fluid extract of meat (e.g., ''Fluid Extract of Beef'') shall contain not more than 50 percent of moisture.

Subpart R—Meat Salads and Meat Spreads

§ 319.760 Deviled ham, deviled tongue, and similar products.

(a) ''Deviled Ham'' is a semiplastic cured meat food product made from finely comminuted ham and containing condiments. Mechanically Separated (Species) may be used in accordance with § 319.6. Deviled ham may contain added ham fat: *Provided*, That the total fat content shall not exceed 35 percent of the finished product. The moisture content of deviled ham shall not exceed that of the fresh unprocessed meat.

(b) The moisture content of ''Deviled Tongue'' and similar products shall not exceed that of the fresh, unprocessed meat.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.761 Potted meat food product and deviled meat food product.

''Potted Meat Food Product'' and ''Deviled Meat Food Product'' shall not contain cereal, vegetable flour, nonfat dry milk, or similar substances. The amount of water added to potted meat food product and deviled meat food product shall be limited to that necessary to replace moisture lost during processing.

§ 319.762 Ham spread, tongue spread, and similar products.

''Ham Spread,'' ''Tongue Spread,'' and similar products shall contain not less than 50 percent of the meat ingredient named, computed on the weight of the fresh meat. Other meat and fat may be used to give the desired spreading consistency provided it does not detract from the character of the spreads named. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

Subpart S—Meat Baby Foods [Reserved]

Subpart T—Dietetic Meat Foods [Reserved]

Subpart U—Miscellaneous

§ 319.880 Breaded products.

The amount of batter and breading used as a coating for breaded product shall not exceed 30 percent of the weight of the finished breaded product.

§ 319.881 Liver meat food products.

Meat food products characterized and labeled as liver products such as liver loaf, liver cheese, liver spread, liver mush, liver paste, and liver pudding shall contain not less than 30 percent of pork, beef, sheep, or goat livers computed on the fresh weight of the livers.

[36 FR 12004, June 24, 1971]

PART 320—RECORDS, REGISTRATION, AND REPORTS

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15603, Oct. 3, 1970, unless otherwise noted.

§ 320.1 Records required to be kept.

(a) Every person (including every firm or corporation) within any of the classes specified in paragraph (a) (1), (2), or (3) of this section is required by the Act to keep records which will fully and correctly disclose all transactions involved in his or its business subject to the Act:

(1) Any person that engages, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as a meat broker, wholesaler, or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

(b) The required records are:

(1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any livestock or carcass, part thereof, meat or meat food product is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act:

(i) The name or description of the livestock or article;

(ii) The net weight of the livestock or article;

(iii) The number of outside containers (if any);

(iv) The name and address of the buyer of livestock or article sold by such person, and the name and address of the seller of livestock or articles purchased by such person;

(v) The name and address of the consignee or receiver (if other than the buyer);

(vi) The method of shipment;

(vii) The date of shipment; and

(viii) The name and address of the carrier.

(ix) In the case of a person belonging to the class specified in paragraph (a)(1), and engaged, for commerce, in the business of slaughtering any swine for use as human or animal food, the name and address (including the city and state, or the township, county, and state) of each person from whom the person belonging to the class so specified purchased or otherwise obtained each swine, and the telephone number, if available, of the person from whom the swine were purchased or otherwise obtained, and all serial numbers and other approved means of identification appearing on all test swine selected at antemortem inspection by FSIS representatives for residue testing.

(2) Shipper's certificates and permits required to be kept by shippers and carriers of articles under part 325 of this subchapter.

(3) A record of seal numbers required to be kept by consignees of inedible products shipped under unofficial seals under § 325.11(b) or (e) of this subchapter, and a record of new consignees of inedible products diverted under § 325.11(e) of this subchapter.

(4)(i) In the case of raw ground beef products, official establishments and retail stores are required to keep records that fully disclose:

(A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product;

(B) All supplier lot numbers and production dates;

(C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next;

(D) The date and time each lot of raw ground beef product is produced; and

(E) The date and time when grinding equipment and other related food-contact surfaces are cleaned and sanitized.

(ii) Official establishments and retail stores covered by this part that prepare ground beef products that are ground at an individual customer's request must keep records that comply with paragraph (b)(4)(i) of this section.

(iii) For the purposes of this section of the regulations, a lot is the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean up, during which the same source materials are used.

(5) Guaranties provided by suppliers of packaging materials under § 317.24.

(6) Records of canning as required by part 431 of this chapter.

(7) Records of nutrition labeling as required by subpart B, part 317, of this subchapter.

(8) Records as required in § 318.23(b) and (c).

(9) Records documenting the development, implementation, and maintenance of procedures for the control of the production process using advanced meat/bone separation machinery and meat recovery systems as required by § 318.24 of this subchapter.

(10) Records of labeling, product formulas, processing procedures, and any additional documentation needed to show that the labels are consistent with the Federal meat and poultry regulations and policies on labeling, as prescribed in § 412.1 of this chapter.

(Approved by the Office of Management and Budget under control number 0583–0015)

[35 FR 15603, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 320.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 320.2 Place of maintenance of records.

(a) Except as provided in paragraph (b) of this section, any person engaged in any business described in § 320.1 and required by this part to keep records must maintain such records at the place where such business is conducted, except that if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records must be kept in a safe place at the prescribed location in accordance with good commercial practices.

(b) Records required to kept under § 320.1(b)(4) must be kept at the location where the raw beef was ground.

[80 FR 79250, Dec. 21, 2015]

§ 320.3 Record retention period.

(a) Except as provided in paragraphs (b) and (c) of this section, every record required to be maintained under this part must be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part.

(b) Records of canning as required in subpart G of part 318 of this chapter, must be retained as required in § 318.307(e); except that records required by § 318.302(b) and (c) must be retained as required by those sections.

(c) Records required to be maintained under § 320.1(b)(4) must be retained for one year.

[80 FR 79250, Dec. 21, 2015]

§ 320.4 Access to and inspection of records, facilities and inventory; copying and sampling.

Representatives of the Secretary afforded access to a business specified in § 320.1 of this part (see § 300.6(b)(2) of this chapter) also must be afforded any necessary facilities (other than reproduction equipment) for the examination and copying of records and for the examination and sampling of inventory.

[69 FR 254, Jan. 5, 2004]

§ 320.5 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business in or for commerce, as a meat broker, renderer, or animal food manufacturer, or engages in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, or any livestock, whether intended for human food or other purposes, or engages in business as a public warehouseman storing any such articles in or for commerce, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any such livestock that died otherwise than by slaughter, shall register with the Administrator, giving such information as is required, including his name, and the address of each place of business at which, and all trade names under which he conducts such business, by filing with the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, a form containing such information within 90 days after the effective date hereof or after such later date as he begins to engage in such business if not engaged therein upon said effective date. All information submitted shall be current and correct. The registration form shall be obtained from Evaluation and Enforcement Division, Office of Program Evaluation, Enforcement, and Review, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, or by calling the District Office.

(b) Whenever any change is made in the name of, or address of any place of business at which, or any trade name under which a registrant conducts his business, he shall report such change in writing to the Administrator within 15 days after making the change.

(c) The registration requirements prescribed in this section shall not apply to persons conducting any of the businesses specified in this section only at an official establishment.

[35 FR 15603, Oct. 3, 1970, as amended at 57 FR 53982, Nov. 16, 1992; 69 FR 254, Jan. 5, 2004]

§ 320.6 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection, as may be required by the Administrator in special cases.

(b) The operator of each official establishment shall report quarterly the number of pounds of meat and meat food product produced at that establishment. The report shall be made on a form furnished by the Administrator and shall be submitted to an inspector at the establishment. Each report shall cover a calendar quarter and shall be filed within 15 days after the end of each quarter.

(c) The operator of each official establishment shall also make such other reports as the Administrator may from time to time require under the Act.

[35 FR 15603, Oct. 3, 1970, as amended at 45 FR 76968, Nov. 21, 1980; 61 FR 38866, July 25, 1996]

§ 320.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Whenever the consignee of any product which bears an official inspection legend refuses to accept delivery of such product on the grounds that it is adulterated or misbranded, the consignee shall notify the Inspector in Charge, Meat and Poultry Inspection

Program, Food Safety and Inspection Service, U.S. Department of Agriculture, of the kind, quantity, source, and present location of the product and the respects in which it is alleged to be adulterated or misbranded, and it will be a violation of the Act for any person to sell or transport, or offer for sale or transportation, or receive for transportation, in commerce, any such product which is capable of use as human food and is adulterated or misbranded at the time of such sale, transportation, offer, or receipt: *Provided, however,* That any such allegedly adulterated or misbranded product may be transported to the official establishment from which it had been transported, in accordance with § 325.10 of this subchapter.

PART 321—COOPERATION WITH STATES AND TERRITORIES

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 321.1 Assistance to State and Territorial programs.

(a) The Administrator is authorized under paragraph (a) of section 301 of the Act, when he determines it would effectuate the purposes of the Act, to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering the meat inspection program of such jurisdiction with a view to assuring that it imposes and enforces requirements at least equal to those under Titles I and IV of the Act, with respect to establishments at which products are prepared for use as human food solely for distribution within such jurisdiction, and with respect to the products of such establishments. Such cooperation is authorized if the jurisdiction has enacted a law imposing mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements at least equal to the Federal requirements with respect to all or certain classes of persons engaged in slaughtering livestock or otherwise preparing products solely for distribution within such jurisdiction.

(b) The Administrator is also authorized under paragraph (a) of section 301 of the Act to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering programs under the laws of such jurisdiction containing authorities at least equal to those in Title II of the Act (relating to records; registration of specified classes of operators; dead, dying, disabled, or diseased livestock; and products not intended for human food), when he determines that such cooperation would effectuate the purposes of the Act.

(c) Such cooperation may include advisory assistance, technical and laboratory assistance and training, and financial aid. The Federal contribution to any State (or Territory) may not exceed 50 percent of the estimated total cost of the cooperative State (or Territorial) program. A cooperative program under this section is called a State-Federal program.

[35 FR 15604, Oct. 3, 1970]

§ 321.2 Cooperation of States in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of any State in carrying out Federal functions under the Federal Meat Inspection Act. A cooperative program for this purpose is called a Federal-State program.

[35 FR 15604, Oct. 3, 1970]

§ 321.3 Cooperation of States for the interstate shipment of carcasses, parts of carcasses, meat, and meat food products.

(a) The Administrator is authorized under 21 U.S.C. 683(b) to coordinate with States that have meat inspection programs as provided in § 321.1 of this part to select certain establishments operating under these programs to participate in a cooperative program to ship carcasses, parts of carcasses,

meat, and meat food products in interstate commerce. A cooperative program for this purpose is called a ''cooperative interstate shipment program.''

(b) Establishments selected to participate in a cooperative interstate shipment program described in this section must receive inspection services from designated State personnel that have been trained in the enforcement of the Act. If the designated personnel determine that the carcasses, parts of carcasses, meat, and meat food products prepared in establishments selected to participate in the cooperative interstate shipment program comply with all requirements under the Act, these items will bear an official Federal mark of inspection and may be shipped in interstate commerce. The Administrator will assign an FSIS ''selected establishment coordinator,'' who will be an FSIS employee, to each State that participates in a cooperative interstate shipment program to provide Federal oversight of the program and enforcement of the program's requirements. The Federal contribution for inspection services provided by States that enter into a cooperative interstate shipment program under this section will be at least 60 percent of eligible State costs. Eligible State costs are those costs that a State has justified and FSIS has approved as necessary for the State to provide inspection services to selected establishments in the State.

(c) Part 332 of this subchapter prescribes conditions under which States and establishments may participate in the cooperative interstate shipment program.

(d) The Administrator will terminate a cooperative interstate shipment agreement with a State if the Administrator determines that the State is not conducting inspection at selected establishments in a manner that complies with the Act and the implementing regulations in this chapter.

[76 FR 24752, May 2, 2011]

PART 322—EXPORTS [1]

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15604, Oct. 3, 1970, unless otherwise noted.

§ 322.1 Marking products for export.

(a) When authorized by inspection personnel, establishment personnel must mark the outside container of any inspected and passed product for export, the securely enclosed pallet within the consignment, or closed means of conveyance transporting the consignment, with a mark that contains a unique identifier that links the consignment to the export certificate or an official mark as described in § 312.8 of this chapter. Ship stores, small quantities exclusively for the personal use of the consignee and not for sale or distribution, and shipments by and for the U.S. Armed Forces, are exempt from the requirements of this section.

(b) When authorized by inspection personnel, establishments must mark each tank car of inspected and passed lard or similar edible product, and each door of each railroad car or other closed means of conveyance, containing inspected and passed loose product shipped directly to a foreign country, with an export inspection mark as shown in § 312.8 of this subchapter.

[81 FR 42233, June 29, 2016]

§ 322.2 Export certification.

(a) Exporters must apply for export certification of inspected and passed

[1] Attention is directed to the requirements of part 325 of this subchapter, governing transportation, and to the requirements of § 318.8 of this subchapter that products prepared under that section for export be destroyed for food purposes before being sold or offered for sale for domestic use.

products shipped to any foreign country. Exporters may apply for an export certificate using a paper or electronic application. FSIS will assess exporters that submit an electronic application the charge in §350.7(e) of this chapter.

(b) FSIS will issue only one certificate for each consignment, except in the case of error in the certificate or loss of the certificate originally issued. A request for a replacement certificate, except in the case of a lost certificate, must be accompanied by the original certificate. The new certificate will carry the following statement: ''Issued in replacement of _____'', with the numbers of the certificates that have been superseded.

(c) FSIS will deliver a copy of the certificate to the exporter. The exporter may furnish the copy of the certificate to the consignee for purposes of affecting the entry of product into the foreign country of destination.

(d) FSIS will retain a copy of the certificate.

(e) Exporters may request inspection personnel to issue certificates for export consignments of product of official establishments not under their supervision, provided the consignments are first identified as having been ''U.S. inspected and passed,'' are found to be neither adulterated nor misbranded, and are marked as required by §322.1.

[81 FR 42234, June 29, 2016]

§322.3 Transferring products for export.

When inspected and passed products for export are transferred from tank cars to other containers on vessels, such transfer shall be done in accordance with the provisions of part 350 of subchapter B of this chapter.

§322.4 Clearance of vessels and transportation without certificate prohibited; exceptions.

No clearance shall be given to any vessel having on board any product destined to any foreign country, and no person operating any vessel, and no railroad or other carrier, shall receive for transportation or transport from the United States to any foreign country, any products, unless and until an official export certificate covering the same has been issued and delivered as provided in this part; except in the case of inspected and passed ship stores and not more than 50 pounds of inspected and passed product for the exclusive personal use of the consignee and not for sale or distribution, and except for exempted product eligible for exportation under the provisions of the Act and the regulations in this subchapter and inedible product that is not capable of use as human food and is eligible for exportation under other provisions of said regulations.

[38 FR 18868, July 16, 1973]

§322.5 Uninspected tallow, stearin, oleo oil, etc., not to be exported unless certified as prescribed.

No tallow, stearin, oleo oil, or the rendered fat derived from the carcasses of livestock, that has not been inspected and passed, and so marked in compliance with the regulations in this subchapter shall be exported, unless the product has been denatured as required by §314.5 or §325.13 of this subchapter or identified and marked as prescribed by §325.11 of this subchapter.

[35 FR 15604, Oct. 3, 1970, as amended at 47 FR 17274, Apr. 22, 1982]

PART 325—TRANSPORTATION

Sec.

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15605, Oct. 3, 1970, unless otherwise noted.

§ 325.1 Transactions in commerce prohibited without official inspection legend or certificate when required; exceptions; and vehicle sanitation requirements.

(a) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any product which is capable of use as human food unless the product and its container, if any, bear the official inspection legend as required under parts 316 and 317 of this subchapter or such product is exempted from the requirement of inspection under part 303 of this subchapter.

(b)(1) No carrier shall transport or receive for transportation in commerce (including transportation in the course of importation) and no person shall offer for transportation any carcass, part thereof, meat or meat food product until a certificate, if required for such transportation by this part, is made and furnished to the carrier in one of the forms prescribed in this part.

(2) Product imported into the United States may be transported and offerred or received for transportation if such product is conveyed in railroad cars, trucks or other means of conveyance, prior to inspection, to an authorized place of inspection, as provided in § 327.6 of this part.

(c) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, meat or meat food products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation in commerce or in any State designated under § 331.2 of this subchapter, any such meat or meat food product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated. Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment. The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Program's discretion and shall be adequate to determine if product in such conveyance is, or when moved could become, adulterated. Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of

conveyance found upon such inspection to be in such condition that product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected. Product placed in any means of conveyance that is found by the inspector to be in such condition that the product may have become adulterated shall be removed from the means of conveyance and handled in accordance with § 318.2(d) of this subchapter.

[35 FR 15605, Oct. 3, 1970, as amended at 41 FR 23700, June 11, 1976; 47 FR 17274, Apr. 22, 1982; 56 FR 65180, Dec. 16, 1991]

§ 325.2 Parcel post and ferries deemed carriers.

(a) For the purposes of this subchapter, the United States parcel post shall be deemed a carrier, and the provisions of this subchapter relating to transportation by carrier shall apply, so far as they may be applicable, to transportation by parcel post.

(b) For the purposes of this subchapter, the operator of every ferry shall be deemed a carrier, and the provisions of this subchapter relating to transportation by carrier shall apply to transportation by ferry of any products loaded on a truck or other vehicle, or otherwise moved by such ferry.

§ 325.3 Product transported within the United States as part of export movement.

When any shipment of any product is offered to any carrier for transportation within the United States as a part of an export movement, the same certificate shall be required as if the shipment were destined to a point within the United States.

§ 325.4 [Reserved]

§ 325.5 Unmarked inspected product transported under official seal between official establishments for further processing; certificate.

(a) Any product which has been inspected and passed may be transported from one official establishment to another for further processing without each article being marked with the official inspection legend, if it is so transported in a railroad car, motortruck, or other means of conveyance which is sealed by a Program employee with an official seal of the Department prescribed in § 312.5(a) of this subchapter. Unless 25 percent or more of the contents of each car or other means of conveyance consists of product not marked with the inspection legend, transportation will not be permitted under this paragraph.

(b) When articles are offered for transportation under paragraph (a) of this section, the initial carrier shall require, and the shipper shall make in duplicate and deliver to the carrier, one copy of a certificate in the following form: [1]

Date _____, 19___
Name of carrier _____
Establishment number of consignor _____
Point of shipment _____
Establishment number of consignee _____
Destination _____
Car number and initials _____
License number of other means of conveyance _____

I hereby certify that the following described product has been U.S. inspected and passed by the U.S. Department of Agriculture; and that it is not marked ''U.S. inspected and passed,'' but has been placed in the means of conveyance specified above under the supervision of an employee of the Meat and Poultry Inspection Programs of said Department, and the means of conveyance has been sealed by him with official U.S. Government seals Nos. ____ and ____.

Kind of product	Amount and weight

(Signature of shipper)

(Address of shipper)

When paunches are offered for transportation under this paragraph, the initial carrier shall require, and the shipper shall make in duplicate and deliver to the carrier, one copy of a certificate in duplicate in the form set out in § 325.5(b), appropriately modified. Certificates in this form or copies thereof need not be forwarded to any official or office of the Department, but the original of the certificate shall be retained by the carrier and a copy

[1] For convenience in filing, it is requested that these certificates be made on paper 5½ × 8 inches in size.

shall be retained by the shipper in accordance with part 320 of this subchapter. If the shipper is also the carrier, he shall nevertheless execute and retain the certificate in accordance with part 320 of this subchapter.

(c) The signature of the shipper or his agent shall be written in full. This certificate may be stamped upon or incorporated in any form ordinarily used in the transportation of product. Certificates in this form or copies thereof need not be forwarded to any official or office of the Department. The original of the certificate required by this section shall be retained by the carrier and a copy shall be retained by the shipper in accordance with part 320 of this subchapter. If the shipper is also the carrier, he shall nevertheless execute and retain the certificate in accordance with part 320 of this subchapter.

§ 325.6 Shipment of paunches between official establishments under official seal; certificate.

Cattle and sheep paunches which have been made clean and from which the mucous membrane has not been removed may be transported from one official establishment to another official establishment for further processing, only under an official seal of the Department as prescribed in § 312.5(a) of this subchapter.

§ 325.7 Shipment of products requiring special supervision between official establishments under official seal; certificate.

(a) Products passed for cooking, and beef that is to be refrigerated to destroy cysticerci, may be shipped loose from one official establishment to any other official establishment, for further handling in accordance with part 318 of this subchapter, in railroad cars, trucks, or other means of conveyance sealed with the official seal of the Department as prescribed in § 325.16: *Provided*, That in the case of railroad cars, the receiving establishment has railroad facilities for unloading the products directly into the establishment.

(b) When such restricted product is shipped from one official establishment to another official establishment in the same railroad car or other means of conveyance with other product, such restricted product shall be packed in individual closed containers as hereinafter provided. Containers shall be sealed by firmly applying a pressure sensitive tape around each container in two directions and stamping the intersection of the tape with the marking device described in § 312.2(a) of this subchapter for use on burlap, muslin, etc. (2½-inch rubber brand). Such tape must possess the adhesive property to actually remove a portion of the container surface when the tape is removed. Alternatively, an inelastic, nonmetallic strap which will retain a legible imprint of the marking device (2½-inch rubber brand) may be used. The imprint of the marking device shall be placed partially on the strap and partially on the container. Such restricted product shall be marked ''U.S. passed for cooking'' or ''pork product ____ °F. ____days refrigeration'' or ''beef passed for refrigeration,'' as the case may be. In addition, a ''U.S. retained'' tag shall be securely affixed to each container of product passed for cooking and of beef passed for refrigeration. The means of conveyance shall not be sealed unless at least 25 percent of the other product in the vehicle is unmarked. For each consignment there shall be promptly issued and forwarded by the inspector to the inspector in charge at destination, a report on the form entitled ''Notice of Unmarked Meats Shipped in Sealed Cars,'' appropriately modified to show the character of the containers, and that the contents are restricted. A duplicate copy shall be retained in the program files.

(c) When products are offered for transportation under this section, the initial carrier shall require and the shipper shall make in duplicate and deliver to the carrier one copy of a certificate in the form set out in § 325.5(b). Certificates in this form or copies thereof need not be forwarded to any official or office of the Department, but the original of the certificate shall be retained by the carrier and a copy shall be retained by the shipper in accordance with part 320 of this subchapter. If the shipper is also the carrier, he shall nevertheless execute and

retain the certificate in accordance with part 320 of this subchapter.

[35 FR 15605, Oct. 3, 1970, as amended at 39 FR 20187, June 7, 1974; 83 FR 25307, May 31, 2018]

§ 325.8 Transportation and other transactions concerning certain undenatured lungs or lung lobes from official establishments or in commerce; provisions and restrictions.

(a) Lungs or lung lobes, other than those condemned under § 310.16(b) of this subchapter, that are prepared at any official establishment, may be sold, transported, offered for sale or transportation, or received for transportation from the establishment, in commerce or otherwise, without denaturing as prescribed in § 314.1 or § 314.3 of this subchapter: *Provided:*

(1) The lungs or lung lobes are sold, transported, or offered for sale or transportation to, or received for transportation by: An animal food manufacturer for use in manufacturing animal food; a zoo, mink farm, or other establishment for use as animal food without further processing; a warehouse in the United States for storage and subsequent movement to such a manufacturer or establishment in the United States, or from one warehouse to another for the account of and subsequent movement to such a manufacturer or establishment, or for export, for nonhuman food purposes.

(2) The boxes or other containers used for shipping the undenatured lungs or lung lobes are closed with nylon filament tape, metallic on nonmetallic straps, round wire, or other similar materials that securely effect closure of such containers, and the containers are permanently identified in at least 2-inch (5 cm) high lettering with the statement ''(Species) Lungs—Not Intended for Human Food.'' In lieu of securely closing the immediate container with any of the above materials, a 1-inch (2.5 cm) wide bright orange band, imprinted around the length and width of the container may be used.

(3) The name and place of business of the packer or distributor shall be shown on the immediate container of the product. In addition, the country of origin shall be shown on the immediate container of imported lungs or lung lobes.

(b) Lungs or lung lobes, other than those condemned under a State law or regulation at least equal to § 310.16(b) of this subchapter, that are prepared at any State inspected establishment may be sold, transported, offered for sale, or transportation or received for transportation from that establishment, in commerce, without denaturing as prescribed under section 201 of the Act, provided the State law or regulations permit such disposition and provided there is compliance with the provisions of paragraph (a) of this section.

(c) Foreign establishments shall be eligible to export lungs or lung lobes, other than those condemned for reasons set forth in § 310.16(b) of this subchapter, to the United States from such foreign country under this section, only if such establishments are certified and approved for export of products to the United States under part 327 of this subchapter, and such product complies with the applicable regulations for preventing the introduction into the United States of diseases (9 CFR 94), in addition to the requirements of paragraph (a) of this section.

(d) All such lungs or lung lobes, if intended for animal food, are subject to the Federal Food, Drug, and Cosmetic Act.

[43 FR 43445, Sept. 26, 1978]

§ 325.9 [Reserved]

§ 325.10 Handling of products which may have become adulterated or misbranded; authorization and other requirements.

(a) When it is claimed that any inspected and passed product, marked with an inspection legend, has become adulterated or misbranded after it has been transported from an official establishment, such product may be transported in commerce to an official establishment after oral permission is obtained from the area supervisor of the area in which that offical establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person

desiring to handle the product. The transportation shall be authorized only for the purpose of officially determining if the product has become adulterated or misbranded and making the appropriate disposition. The area supervisor shall make a record of the authorization and such other information which will effectively identify the shipment and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(b) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by a Program inspector, and if it is found that the article is not adulterated, the same may be received into the establishment; but if the article is found to be adulterated, it shall at once be stamped ''U.S. inspected and condemned'' and disposed of in accordance with part 314 of this subchapter, and if it is found to be misbranded, it shall be handled in accordance with §318.2(d) of this subchapter: *Provided,* That when a product is found to be affected with one of the correctable conditions specified in §318.2(d) of this subchapter, in respect to which rehandling is permitted, it may be transported from the official establishment to another official establishment for such rehandling as is necessary to assure that the product is not adulterated or misbranded when finally released. The transportation of such a product from an official establishment shall be done in a manner prescribed in each specific case by the Administrator.

[35 FR 15605, Oct. 3, 1970, as amended at 47 FR 17274, Apr. 22, 1982]

§ 325.11 Inedible articles: denaturing and other means of identification; exceptions.

(a) Except as provided in §325.8 and §325.10, no carcass, part of a carcass, rendered grease, tallow, or other fat derived from the carcasses of livestock, or other meat food product, that has not been inspected and passed at an official establishment under the provisions of this subchapter and is not exempted from such inspection, and no carcass, part of a carcass, fat or other meat food product that is adulterated or misbranded, shall be offered for transportation in commerce by any person unless it is handled in accordance with paragraph (b), (c), (d), or (e) of this section or is denatured or otherwise identified as prescribed in §325.13, §314.1, §314.3, §314.9, §314.10, or §314.11 of this subchapter.

(b) Inedible rendered animal fats from official or other establishments in the United States having the physical characteristics of a meat food product fit for human food may be transported in commerce without denaturing, if the following conditions are met:

(1) Such inedible rendered fat shall not be bought, sold, transported, or offered for sale or offered for transportation in commerce, or imported, except by rendering companies, dealers, brokers, or others who obtain a numbered permit for such activities from the Regional Director.

(2) Such inedible rendered animal fat may be so distributed only if consigned to a domestic manufacturer of technical articles other than for human food or to an export terminal for exportation or storage for exportation as an inedible article, and provided, in the case of such fat consigned to a domestic manufacturer, the product is for use solely by the consignee for manufacturing purposes of nonhuman food articles and may not be further sold or shipped without first receiving approval of the Regional Director: *And provided further,* That such fat intended for export and stored at a terminal point prior to export will be subject to review by Program employees to assure that it is exported as inedible.

(3) When transported in commerce, or imported, such inedible rendered fat shall be marked conspicuously with the words ''technical animal fat not intended for human food'' on the ends of the shipping containers, in letters not less than 2 inches high; in the case of shipping containers such as drums, tierces, barrels, and half barrels, and not less than 4 inches high in the case of tank cars and trucks. All shipping containers shall have both ends painted with a durable paint, if necessary, to provide a contrasting background for the required marking.

(4) Such inedible rendered fat shall be transported only in sealed shipping

containers bearing unofficial seals applied by the shipper, which shall include the identification number assigned by said Director for the permit holder. The number shall appear on the bill of lading or other transportation documents for the shipment. The consignees in the United States must retain the seals in their records as prescribed in part 320 of this subchapter.

(5) Any diversion or effort to divert inedible rendered fat contrary to the provisions of this paragraph (b) or other violation of the provisions of this section may result in the revocation of the permit for shipment of technical animal fat at the discretion of the Administrator.

(c) Inedible rendered animal fat derived from condemned or other inedible materials at official or other establishments in the United States may be transported in commerce if mixed with low grade offal or other materials which render the fat readily distinguishable from an article of human food, and if the outside container bears the word ''inedible.''

(d)(1) Except as provided in paragraphs (d)(2), (3), and (4) of this section, or in §§ 314.10 and 314.11 of this subchapter, no animal food prepared, in whole or in part, from materials derived from the carcasses of livestock in an official establishment or elsewhere, shall be bought, sold, transported, offered for sale or transportation, or received for transportation, in commerce, or imported, unless:

(i) It is properly identified as animal food;

(ii) It is not represented as being a human food; and

(iii) It has been denatured as prescribed in § 325.13(a)(2) so as to be readily distinguishable from an article of human food.

(2) Notwithstanding the provisions of paragraph (d)(1) of this section, an animal food that consists of less than 5 percent of parts or products of the carcasses of livestock and that is not represented by labeling or appearance or otherwise as being a human food or as a product of the meat food industry need not be denatured in accordance with § 325.13(a)(2).

(3) Notwithstanding the provisions of paragraph (d)(1) of this section, animal food packed in hermetically sealed, retort processed, conventional retail-size containers, and retail-size packages of semi-moist animal food need not be denatured in accordance with § 325.13(a)(2) if the name of the article clearly conveys the article's intended use for animal food and appeared on the label in a conspicuous manner.

(i) Except as provided in paragraph (ii) of paragraph (d)(3), the name of the article must be stated on the label as ''Animal Food,'' ''Pet Food,'' or ''(name of species) Food'' (e.g., ''Dog Food'' or ''Cat Food''). To be considered conspicuous, the name of the article, wherever it appears on the label, must be in letters at least twice as high, wide, and thick as the letters indicating the presence in the article of any ingredients derived from the carcasses of livestock.

(ii) Notwithstanding the provisons of paragraph (i) of this paragraph (d)(3), the article's name may be stated on the label to show that it is or contains livestock-source material and that the article is for animals; e.g., ''Horsemeat for Pets'' or ''Beef Stew for Dogs'': *Provided,* That the entire name of the article is stated, wherever it appears on the label, as an individual, contiguous unit, whether stated on a single line or more than one line, and the letters denoting the article's intended use for animal food are at least as high, wide, and thick as the letters indicating the presence of material derived from any livestock carcass. However, when the label bears on its principal display panel a vignette which pictures, in clearly recognizable form and size, one or more animals of the species for which the article's name indicates the article is intended, the letters used to state the article's intended use shall be at least one-half as high, wide, and thick as the letters used in the article's name or other letters indicating the presence of material derived from any livestock carcass, but shall not be less than ⅛ inches high. The letters used to state the article's intended use may be separated from the article's name by the vignette.

(iii) Letters used to denote the intended use of the article must contrast as markedly with their background as the letters indicating the presence in

the article of livestock carcass-source material contrast with their background.

(4) The requirements of this part do not apply to livestock or poultry feeds manufactured from processed livestock byproducts (such as meat meal tankage, meat and bone meal, blood meal, and feed grade animal fat), or to processed dry animal food.

(e) Except for inedible rendered animal fats and lungs or lung lobes, inedible products (including condemned products only if condemned for causes specified in §314.11 of this subchapter) which were prepared at any official establishment, or at any State inspected establishment in any State not listed in §331.2 of this subchapter, and which have the physical characteristics of a product fit for human food, may be transported from an official establishment or in commerce, without denaturing as required by this subchapter, if the following conditions are met:

(1) The shipper must have obtained a numbered permit for such activity from the appropriate Regional Director, as identified in §301.2 of this subchapter. Such permit may be obtained upon written application to the appropriate Regional Director and his determination that the proposed transportation would be authorized under this paragraph (e). The application shall state the name and address of the applicant, a description of the type of his business operations, and the purpose of making such application.

(2) Such inedible products may be transported under this paragraph (e) only if consigned to a manufacturer in the United States of articles other than for human food and if the product is for use solely by the consignee for manufacturing articles not for human food. Such products may not be transported in commerce to any consignee other than the one to which they were originally shipped unless prior notice of the diversion is given to the appropriate Regional Director and a record identifying the new consignee is maintained by the shipper as required by §320.1 of this subchapter.

(3) When transported from an official establishment or in commerce under this paragraph (e), the outside container of such inedible products shall be marked conspicuously with the words ''Inedible—Not Intended for Human Food'' in letters not less than 2 inches high, in the case of containers, such as cartons, drums, tierces, barrels, and half barrels, and not less than 4 inches high in the case of tank cars and trucks used to transport such products not in other containers.

(4) Such inedible products shall be transported from an official establishment or in commerce under this paragraph (e) only in railroad cars, trucks, or containers which bear unofficial seals applied by the shipper, which shall include the identification number assigned to the permit holder and an individual seal serial number assigned by the shipper; and the product so transported shall be accompanied by an invoice or bill of lading specifying the permit holder's identification number. The consignee in the United States must retain a record of the identification and serial numbers shown on the seals in his records as prescribed in part 320 of this subchapter.

(5) Any diversion, or effort to divert, undenatured, inedible product contrary to the provisions of this paragraph (e) or other violation of the provisions of this section may result in the revocation of the permit for shipment of inedible products under this paragraph (e), at the discretion of the Administrator.

[47 FR 17274, Apr. 22, 1982, as amended at 49 FR 47478, Dec. 5, 1984]

§ 325.12 [Reserved]

§ 325.13 Denaturing procedures.

(a) Carcasses, parts thereof, meat and meat food products (other than rendered animal fats) that have been treated in accordance with the provisions of this paragraph shall be considered denatured for the purposes of the regulations in this part, except as otherwise provided in part 314 of this subchapter for articles condemned at official establishments.

(1) The following agents are prescribed for denaturing carcasses, parts thereof, meat or meat food products which are affected with any condition that would result in their condemnation and disposal under part 314 of this subchapter if they were at an official establishment: Crude carbolic acid;

cresylic disinfectant; a formula consisting of 1 part FD&C green No. 3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or other proprietary substance approved by the Administrator in specific cases.[3]

(2) Except as provided in paragraphs (a)(3), (4), and (5) of this section, the following agents are prescribed for denaturing other carcasses, parts thereof, meat and meat food products, for which denaturing is required by this part: FD&C green No. 3 coloring; FD&C blue No. 1 coloring; FD&C blue No. 2 coloring; finely powdered charcoal; or other proprietary substance approved by the Administrator in specific cases.[3]

(3) Tripe may be denatured by dipping it in a 6 percent solution of tannic acid for 1 minute followed by immersion in a water bath, then immersing it for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring;

(4) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and

(5) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

(6) Before the denaturing agents are applied to articles in pieces more than 4 inches in diameter, the pieces shall be freely slashed or sectioned. (If the articles are in pieces not more than 4 inches in diameter, slashing or sectioning will not be necessary.) The application of any of the denaturing agents listed in paragraph (a)(1) or (2) of this section to the outer surface of molds or blocks of boneless meat, meat byproducts, or meat food products shall not be adequate. The denaturing agent must be mixed intimately with all of the material to be denatured, and must be applied in such quantity and manner that it cannot easily and readily be removed by washing or soaking. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food.

(7) Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91).[1]

(b) Inedible rendered animal fats shall be denatured by thoroughly mixing therein denaturing oil, No. 2 fuel oil, brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, finely powdered charcoal, or any proprietary denaturing agent approved for the purpose by the Administrator in specific cases. The charcoal shall be used in no less quantity than 100 parts per million and shall be of such character that it will remain suspended indefinitely in the liquid fat. Sufficient of the chosen identifying agents shall be used to give the rendered fat so distinctive a color, odor, or taste that it cannot be confused with an article of human food.

[35 FR 15605, Oct. 3, 1970, as amended at 41 FR 22930, June 8, 1976; 44 FR 67626, Nov. 27, 1979]

[3] Information as to approval of any proprietary denaturing substance may be obtained from the Technical Services, Meat and Poultry Inspection, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[1] Copies of MP Form 91 may be obtained, without charge, by writing to the Administrative Operations Branch, Food Safety and Inspection Service, U.S. Department of Agriculture, 123 East Grant Street, Minneapolis, Minnesota 55403. Diagrams 2 and 3 of the Meat Denaturing Guide are for comparison purposes only. The Meat Denaturing Guide has been approved for incorporation by reference by the Director, Office of the Federal Register, and is on file at the Federal Register library.

§ 325.14 Certificates, retention by carrier.

All original certificates delivered to a carrier in accordance with this part shall be filed separate and apart from all its other papers and records or identified in such a manner as to be readily checked by Department employees. Every certificate required to be maintained under this part shall be retained for a period of 2 years after December 31 of the year in which the transaction has occurred.

§ 325.15 Evidence of proper certification required on waybills; transfer bills, etc., for shipment by connecting carrier; forms of statement.

(a) All waybills, transfer bills, running slips, conductor's cards, or other papers accompanying a shipment, in the course of importation or otherwise in commerce, of any product shall have embodied therein, stamped thereon, or attached thereto a signed statement which shall be evidence to connecting carriers that the proper shipper's certificate, as required by § 325.5, § 325.6, or § 325.7, is on file with the initial carrier. No connecting carrier shall receive for transportation or transport in the course of importation or otherwise in commerce any product unless the waybill, transfer bill, running slip, conductor's card, or other papers accompanying the same includes the signed statement in the following form:

(Name of transportation company)
U.S. inspected and passed, as evidenced by shipper's certificate on file with initial carrier.
(signed) _____
Agent

(b) Signatures of agents to statements required under this section shall be written in full.

[47 FR 17276, Apr. 22, 1982]

§ 325.16 Official seals; forms, use, and breaking.

(a) The official seals required by this part shall be those prescribed in § 312.5(a) of this subchapter.

(b) Except as provided in § 325.18(b), official seal affixed under this part shall be affixed or broken only by Program employees, and no person other than a Program employee shall affix, detach, break, change, or tamper with any such seal in any way whatever. Commission of any such acts contrary to this regulation is a criminal offense.

§ 325.17 Loading or unloading products in sealed railroad cars, trucks, etc., en route prohibited; exception.

Unloading any product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any product or any other commodity in the means of conveyance while en route from one official establishment to another official establishment is not permitted, except that product transported under § 325.5 from one official establishment to another for further processing may be unloaded and stored in transit at any approved warehouse which is operated under the identification service provided under the regulations in part 350 of subchapter B of this chapter and which has railroad facilities or a receiving dock for unloading the product directly into such warehouse: *Provided,* That the product is stored in rooms which are of such size and type as will not result in adulteration or misbranding of the product: *And provided further,* That the product is transported to and from such warehouse, and under official seal as provided in § 325.5 and stored in such rooms at such warehouse.

§ 325.18 Diverting of shipments, breaking of seals, and reloading by carrier in emergency; reporting to Regional Director.

(a) Shipments of inspected and passed product that bear the inspection legend may be diverted from the original destination without a reinspection of the articles, provided the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with § 325.15.

(b) In case of wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the

shipment may be diverted from the original destination, without another shipper's certificate; but in all such cases the carrier shall immediately report the facts by telephone or telegraph to the Regional Director in the area in which the emergency occurs. Such report shall include the following information:

(1) Nature of the emergency.

(2) Place where seals were broken.

(3) Original points of shipment and destination.

(4) Number and initial of the original car or truck.

(5) Number and initials of the car or truck into which the articles are reloaded.

(6) New destination of the shipment.

(7) Kind and amount of articles.

[35 FR 15605, Oct. 3, 1970, as amended at 42 FR 39087, Aug. 2, 1977]

§ 325.19 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this part do not apply:

(a) To specimens of product sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To material released for educational, research and other nonfood purposes, as prescribed in § 314.9 of this subchapter;

(c) To glands and organs for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in § 318.1(g) of this subchapter;

(d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and

(e) To articles that are naturally inedible by humans, such as hoofs, horns, and hides in their natural state.

§ 325.20 Transportation and other transactions concerning dead, dying, disabled, or diseased livestock, and parts of carcasses of livestock that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, disabled or diseased animals or parts of the carcasses of any animals that died otherwise than by slaughter shall:

(a) Buy, sell, transport, or offer for sale or transportation, in commerce, or import any dead livestock if its hide or skin has been removed;

(b) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any livestock that died otherwise than by slaughter, unless such livestock and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 320 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by the Secretary as one that imposes requirements at least equal to the Federal requirements for purposes of paragraph 301(c) of the Act;[4]

(c) Buy in commerce or import any dead, dying, disabled, or diseased livestock or parts of the carcasses of any livestock that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 320 of this subchapter, or is the operator of an establishment inspected as required by paragraph (b) of this section and such livestock or parts of carcasses are to be delivered to establishments eligible to

[4] A list of such registrants, States, and amendments thereof, will be published in the FEDERAL REGISTER, and information concerning the registration status of particular animal food manufacturers, renderers, or collection stations, or the status of particular States or Territories may also be obtained from the Director, Administrative Management Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

receive them under paragraph (b) of this section;

(d) Unload en route to any establishment eligible to receive them under paragraph (b) of this section, any dead, dying, disabled, or diseased livestock or parts of the carcasses of any livestock that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided*, That any such dead, dying, disabled, or diseased livestock, or parts of carcasses may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier shall immediately report the facts by telegraph or telephone to the Compliance Staff, Meat and Poultry Inspection Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(e) Load into any means of conveyance containing any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any livestock that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any livestock or parts of carcasses not within the foregoing description or any other products or other commodities.

[35 FR 15605, Oct. 3, 1970, as amended at 42 FR 42309, Aug. 23, 1977]

§ 325.21 Means of conveyance in which dead, dying, disabled, or diseased livestock and parts of carcasses thereof shall be transported.

All vehicles and other means of conveyance used by persons subject to § 325.20 for transporting in commerce or importing, any dead, dying, disabled, and diseased livestock or parts of carcasses of livestock that died otherwise than by slaughter shall be leak-proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance so used in conveying such livestock, or parts thereof, shall be cleaned and disinfected prior to use in the transportation of any product intended for use as human food. The cleaning procedure shall include the complete removal from the means of conveyance of any fluid, parts, or product of such dead, dying, disabled, or diseased livestock and the thorough application of a disinfectant to the interior surfaces of the cargo space. Substances permitted for such use are:

(a) ''Liquified phenol'' (U.S.P. strength 87 percent phenol) in the proportion of at least 6 fluid ounces to 1 gallon of water.

(b) ''Cresylic disinfectant'' in the proportion of not less than 4 fluid ounces to 1 gallon of water; and such other disinfectants as are approved by the Administrator in specific cases. The use of ''cresylic disinfectant'' is permitted subject to the conditions prescribed in § 71.10(b) of this title.

PART 327—IMPORTED PRODUCTS

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15610, Oct. 3, 1970, unless otherwise noted.

§ 327.1 Definitions; application of provisions.

(a) When used in this part, the following terms are defined to mean:

(1) *Import (imported).* To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer(ed) for entry.* The point at which the importer presents the imported product for reinspection.

(3) *Entry (entered).* The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection, as required by § 327.26.

(b) The provisions of this part shall apply to products derived from cattle, sheep, swine, goats, horses, mules, and other equines, if capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance with applicable requirements under other laws, including the provisions in parts 94, 95, and 96 of chapter I of this title.

[35 FR 15610, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971; 54 FR 41048, Oct. 5, 1989; 79 FR 56232, Sept. 19, 2014]

§ 327.2 Eligibility of foreign countries for importation of products into the United States.

(a)(1) Whenever it shall be determined by the Administrator that the system of meat inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their products with requirements equivalent to all the inspection, building construction standards, and all other provisions of the Act and the regulations in this subchapter which are applied to official establishments in the United States, and their products, and that reliance can be placed upon certificates required under this part from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, products prepared in such establishments which are certified and approved in accordance with paragraph (a)(3) of this section, shall be eligible so far as this subchapter is concerned for importation into the United States from such foreign country after applicable requirements of this subchapter have been met.

(2) The determination of acceptability of a foreign meat inspection system for purposes of this section shall be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system shall have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of meat inspection in the United States with respect to:

(A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which products are prepared for export to the United States;

(B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system;

(C) The assignment of competent, qualified inspectors;

(D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing meat inspection and to certify

or refuse to certify products intended for export;

(E) Adequate administrative and technical support;

(F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States.

(G) Other requirements of adequate inspection service as required by the regulations in this subchapter.

(ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of meat inspection organized and maintained in the United States with respect to:

(A) Ante-mortem inspection of animals for slaughter and inspection of methods of slaughtering and handling in connection with slaughtering which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of the veterinarians;

(B) Post-mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians;

(C) Official controls by the national government over establishment construction, facilities, and equipment;

(D) Direct and continuous official supervision of slaughtering and preparation of product, by the assignment of inspectors to establishments certified under paragraph (a)(3) of this section, to assure that adulterated or misbranded product is not prepared for export to the United States;

(E) Complete separation of establishments certified under subparagraph (3) of this paragraph from establishments not certified and the maintenance of a single standard of inspection and sanitation throughout all certified establishments;

(F) Requirements for sanitation at certified establishments and for sanitary handling of product;

(G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment;

(H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.

(I) Other matters for which requirements are contained in the Act or regulations in this subchapter.

(iii) Countries desiring to establish eligibility for importation of product into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign meat inspection system is based and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a)(2) (i) and (ii) of this section. Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in paragraphs (a)(2) (i) and (ii) of this section. Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system, including information required by paragraph (e) of section 20 of the Act, as the Administrator may find pertinent to and necessary for the determinations required by this section of the regulations.

(iv) The foreign inspection system must maintain a program to assure that the requirements referred to in this section, equivalent to those of the Federal system of meat inspection in the United States, are being met. The program as implemented must provide for the following:

(A) Periodic supervisory visits by a representative of the foreign inspection system to each establishment certified in accordance with paragraph (a)(3) of this section to ensure that requirements referred to in paragraphs (a)(2)(ii)(A) through (H) of this section are being met: Provided, That such visits are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States;

(B) Written reports prepared by the representative of the foreign inspection

system who has conducted a supervisory visit, documenting his or her findings with respect to the requirements referred to in (A) through (H) of paragraph (a)(2)(ii) of this section, copies of which shall be made available to the representative of the Department at the time of that representative's review upon request by that representative to a responsible foreign meat inspection official: *Provided*, That such reports are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States; and

(C) Random sampling of internal organs and fat of carcasses at the point of slaughter and the testing of such organs and fat, for such residues having been identified by the exporting country's meat inspection authorities or by this Agency as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator: *Provided*, That such testing is required only on samples taken from carcasses from which meat or meat food products intended for importation into the United States are produced.

(3) Only those establishments that are determined and certified to the Agency by a responsible official of the foreign meat inspection system as fully meeting the requirements of paragraphs (a)(2)(i) and (ii) of this section are eligible to have their products imported into the United States. Establishment eligibility is subject to review by the Agency (including observations of the establishments by Program representatives at times prearranged with the foreign meat inspection system officials). Foreign establishment certifications must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may terminate the eligibility of any foreign establishment for the importation of its products into the United States if it does not comply with the requirements listed in paragraphs (a)(2)(i) and (ii) of this section, or if current establishment information cannot be obtained. The Administrator will provide reasonable notice to the foreign government of the proposed termination of any foreign establishment, unless a delay in terminating its eligibility could result in the importation of adulterated or misbranded product.

(i) For a new establishment, or any establishment for which information from last year's electronic certification or paper certificate has changed, the certification or certificate must contain: The date; the foreign country; the foreign establishment's name, address, and foreign establishment number; the foreign official's title and signature (for paper certificates only); the type of operations conducted at the establishment (e.g., slaughter, processing, storage, exporting warehouse); and the establishment's eligibility status (e.g., new or relisted (if previously delisted)). Slaughter and processing establishment certifications must address the species and type of products produced at the establishment (e.g., the process category).

(ii) If the establishment information provided on the preceding year's electronic foreign establishment certification or paper certificate, as required in paragraph (a)(3)(i) of this section, has not changed, the certification or certificate must contain: The date, the foreign country, the foreign establishment's name, and the foreign official's title and signature (for paper certificates only).

(4) Product of cattle, sheep, swine, and goats from foreign countries not listed in paragraph (b) of this section and product of equines from countries not listed in paragraph (c) of this section is not eligible for importation into the United States, except as provided by § 327.16 or § 327.17. The listing of any foreign country under this section may be withdrawn whenever it shall be determined by the Administrator that the system of meat inspection maintained by such foreign country does not assure compliance with requirements equivalent to all the inspection, building construction standards, and other requirements of the Act and the regulations in this subchapter as applied to official establishments in the United States; or that reliance cannot be placed upon certificates required under this part from authorities of such foreign country; or that, for lack of current information concerning the

system of meat inspection being maintained by such foreign country, such foreign country should be required to reestablish its eligibility for listing.

(b) It has been determined that product of cattle, sheep, swine, and goats from the following countries covered by foreign meat inspection certificates of the country of origin as required by §327.4, except fresh, chilled, or frozen or other product ineligible for importation into the United States from countries in which the contagious and communicable disease of rinderpest or of foot-and-mouth disease or of African swine fever exists as provided in part 94 of this title, is eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part.

Argentina, Australia, Austria, Belgium, Belize, Brazil, Canada, Chile, Costa Rica, Czech Republic, Denmark, Dominican Republic, El Salvador, England and Wales, Finland, France, Germany (Federal Republic), Guatemala, Honduras, Hungary, Iceland, Ireland (Eire), Italy, Japan, Lithuania, Mexico, Namibia, Netherlands, New Zealand, Nicaragua, Northern Ireland, Norway, Paraguay, Poland, Republic of China, (Taiwan), Republic of Croatia, Republic of Slovenia, Romania, San Marino,[1] Scotland, Slovakia,[2] Spain, Sweden, Switzerland, Uruguay, Venezuela, Yugoslavia.

(c) It has been determined that product of equines from the following countries, covered by foreign meat inspection certificates of the country of origin as required by §327.4, is eligible under the regulations in this subchapter for importation into the United States after inspection and marking as required by the applicable provisions of this part.

Argentina, Canada, New Zealand, Paraguay.

[35 FR 15610, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §327.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

[1] Equivalent for processing inspection system only.

[2] May export to the United States only processed meat food products derived from animals slaughtered under Federal inspection in the United States, or in a country eligible to export meat and meat products to the United States.

§ 327.3 No product to be imported without compliance with applicable regulations.

(a) No product offered for importation from any foreign country shall be admitted into the United States if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product.

(b) No cooked or partially cooked meat or meat trimmings, either in separable pieces or molded into larger forms, shall be permitted entry except under the following conditions:

(1) A complete procedure for preparing and handling the product in the foreign country and en route to the United States shall be submitted by the exporter or his authorized agent to the Administrator and determined by the Administrator to be adequate to assure that the product will not be adulterated or misbranded at the time of offer for entry.

(2) A system acceptable to the Administrator (upon his determination that the system will provide a reliable indication of the kinds and numbers of microorganisms present) for the microbiological testing of the finished product shall be installed by the processor, the product is subjected to such testing, and the results thereof are furnished to the Administrator and are acceptable to him as showing that the product has been prepared and handled in a sanitary manner.

(c) [Reserved]

[35 FR 15610, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 54 FR 41048, Oct. 5, 1989; 56 FR 38335, Aug. 13, 1991; 57 FR 27906, June 23, 1992]

§ 327.4 Foreign inspection certificate requirements.

(a) Except as provided in §327.16, each consignment imported into the United States must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product.

(b) An official of the foreign government must certify that any product described on any official certificate was produced in accordance with the regulatory requirements in § 327.2.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification mark on the units;

(8) The net weight of each lot; and

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

[79 FR 56233, Sept. 19, 2014]

§ 327.5 Import inspection application.

(a) Applicants must submit an import inspection application, to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted (electronically or on paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 327.16 and 327.17.

[79 FR 56233, Sept. 19, 2014]

§ 327.6 Products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

(a)(1) Except as provided in §§ 327.16 and 327.17, all products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.

(3) The electronic inspection system shall be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic inspection system.

(b) All products, required by this part to be inspected, shall be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section. Such approved official import inspection establishments will be listed in the Directory of Meat

and Poultry Inspection Program Establishments, Circuits and Officials, published by the Food Safety and Inspection Service. The listing will categorize the kind or kinds of product[2] which may be inspected at each official import inspection establishment, based on the adequacy of the facilities for making such inspections and handling such products in a sanitary manner.

(c) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application shall be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, and shall include all information called for by that form.

(d) Approval for Federal import inspection shall be in accordance with part 304 of this subchapter.

(e) Owners or operators of official import inspection establishments must furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 304.2, 307.1, 307.2(b), (d), (f), (h), (k), and (l), and part 416 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment provided that an application has been filed and drawings have been submitted in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may also be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

(i) A sampling inspection shall be made, as provided in paragraph (a) of this section, of foreign chilled fresh or frozen fresh meat, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled fresh or frozen fresh meat shall be the same as those used for domestic chilled fresh or frozen fresh meat. (See § 327.21)

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

[1] [Reserved]

[2] For example: Canned product, boneless meat, carcasses and cuts.

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product on Form MP–410 to Program area supervisors at points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with §318.309 (d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(*c*), (d)(1)(v), (d)(1)(vii) and (d)(1)(viii) of this subchapter. The importers or his/her agent shall provide the necessary incubation facilities in accordance with §318.309(d)(1)(i) of this subchapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this section may be obtained, upon request, from International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[35 FR 15610, Oct. 3, 1970, as amended at 37 FR 21927, Oct. 17, 1972; 38 FR 29215, Oct. 23, 1973; 49 FR 36818, Sept. 20, 1984; 51 FR 37707, Oct. 24, 1986; 51 FR 45633, Dec. 19, 1986; 54 FR 274, Jan. 5, 1989; 54 FR 41048, Oct. 5, 1989; 62 FR 45026, Aug. 25, 1997; 64 FR 56416, Oct. 20, 1999; 64 FR 66545, Nov. 29, 1999; 65 FR 2284, Jan. 14, 2000; 79 FR 56233, Sept. 19, 2014]

§ 327.7 Products for importation; movement prior to inspection; handling; bond; assistance.

(a) No product required by this part to be inspected shall be moved, prior to inspection from any port, or, if arriving by water from the wharf where first unloaded, to any place other than the place designated by, or in accordance with, this part as the place where the same shall be inspected.

(b) No product required by this part to be inspected shall be conveyed, prior to inspection, from any port, or, if arriving by water, from the wharf where first unloaded, in any manner other than in compliance with this part.

(c) No product required by this part to be inspected shall be delivered to the consignee or his agent prior to inspection, unless the consignee shall furnish a bond, in form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through the customs.

(d) The consignee or his agent shall provide such assistance as Program inspectors may require for the handling and marking of product offered for entry.

[35 FR 15610, Oct. 3, 1970, as amended at 37 FR 21928, Oct. 17, 1972; 51 FR 37707, Oct. 24, 1986; 56 FR 65180, Dec. 16, 1991]

§ 327.8 Import products; equipment and means of conveyance used in handling to be maintained in sanitary condition.

Compartments of steamships, sailing vessels, railroad cars, and other means of conveyance transporting any product to the United States, and all trucks, chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any product offered for importation into the United States, shall be maintained in a sanitary condition.

§ 327.9 Burlap wrapping for foreign meat.

Burlap shall not be used as a wrapping for foreign meat unless the meat is first wrapped with a good grade of paper or cloth of a kind which will prevent contamination with lint or other foreign material.

§ 327.10 Samples; inspection of consignments; refusal of entry; marking.

(a) Program inspectors may take, without cost to the United States, for laboratory examination, samples of any product which is subject to analysis, from each consignment offered for importation, except that such samples shall not be taken of any product offered for importation under §327.16.

(b) Except for product offered for entry from Canada, the outside containers of all products offered for entry from any foreign country and accompanied with a foreign inspection certificate as required by this part, which, upon reinspection by import inspectors are found not to be adulterated or misbranded and are otherwise eligible for

entry into the United States under this part, or the products themselves if not in containers, shall be marked with the official inspection legend prescribed in § 327.26 of this part. Except for Canadian product, all other products so marked, in compliance with this part, shall be entered into the United States, insofar as such entry is regulated under the Act.

(c) Product which is inspected and rejected shall be marked ''U.S. Refused Entry'' as shown in § 327.26(c). Such marks shall be applied to the shipping container or the product itself if not in a container.

(d) The inspection legend may be placed on containers of product before completion of official import inspection if the containers are being inspected by an import inspector who reports directly to an Import Field Office Supervisor; the product is not required to be held at the establishment pending the receipt of laboratory test results; and a written procedure for controlled stamping, submitted by the import establishment and approved by the Director, Import Inspection Division, is on file at the import inspection facility where the inspection is to be performed.

(1) The written procedure for controlled pre-stamping should be in the form of a letter and shall include the following:

(i) That stamping under this part will be limited to those lots of product which can be inspected on the day that certificates for the product are examined;

(ii) That all product which has been pre-stamped will be stored in the facility where the import inspection will occur;

(iii) That inspection marks applied under this part will be removed from any lot of product subsequently refused entry on the day the product is rejected; and

(iv) That the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of origin, the foreign establishment number, the product name, the number of units, the shipping container marks, and the MP–410 number covering the product to be inspected. The daily stamping log must be retained by the establishment in accordance with the requirements of § 320.3.

(2) An establishment's controlled pre-stamping privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this part or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping privilege has been cancelled may appeal the decision to the Administrator, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the controlled pre-stamping privilege was wrongfully cancelled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator. The cancellation of the controlled pre-stamping privilege will be in effect until there is a final determination of the proceeding.

(Approved by the Office of Management and Budget under control number 0583–0015)

[35 FR 15610, Oct. 3, 1970, as amended at 53 FR 17014, May 13, 1988; 54 FR 41048, Oct. 5, 1989]

§ 327.11 Receipts to importers for import product samples.

In order that importers may be assured that samples of foreign products collected for laboratory examination are to be used exclusively for that purpose, official receipts shall be issued and delivered to importers, or their agents, by inspectors for all samples of foreign products collected. The official receipt shall be prepared in duplicate, over the signature of the inspector who collects the samples, and shall show the name of the importer, country of origin, quantity and kind of product collected, date of collection, and that the sample was collected for laboratory

examination. The duplicate copy of the receipt shall be retained by the inspectors as their office record.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986]

§ 327.12 Foreign canned or packaged products bearing trade labels; sampling and inspection.

(a) Samples of foreign canned or packaged products bearing on their immediate containers trade labels which have not been approved under § 317.3 of this subchapter shall be collected and forwarded to the laboratory by the Program inspector for examination, and the products shall be held pending receipt of the report of the laboratory findings and the results of the examination of trade labels and the marks on shipping containers.

(b) Foreign canned or packaged products bearing trade labels and other markings which have been approved under § 317.3 of this subchapter shall be inspected for soundness and checked for net weight. Samples may be collected for laboratory examination, but the products may be released under customs' bond pending the report of laboratory findings.

(c) Samples shall be taken from foreign canned products or packaged products as required by § 327.6 (a) and (j) of this part.

[35 FR 15610, Oct. 3, 1970, as amended at 49 FR 36818, Sept. 20, 1984]

§ 327.13 Foreign products offered for importation; reporting of findings to customs; handling of articles refused entry.

(a)(1) Program inspectors shall report their findings as to any product which has been inspected in accordance with this part, to the Director of Customs at the original port of entry where the same is offered for clearance through Customs inspection.

(2) When product has been identified as ''U.S. refused entry, '' the inspector shall request the Director of Customs to refuse admission to such product and to direct that it be exported by the owner or consignee within the time specified in this section, unless the owner or consignee, within the specified time, causes it to be destroyed by disposing of it under the supervision of a Program employee so that the product can no longer be used as human food, or by converting it to animal food uses, if permitted by the Food and Drug Administration. The owner or consignee of the refused entry product shall not transfer legal title to such product, except to a foreign consignee for direct and immediate exportation, or to an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food purposes. ''Refused entry'' product must be delivered to and used by the manufacturer or renderer within the 45-day time limit. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed as specified in the notice under paragraph (a)(5) of this section.

(3) No lot of product which has been refused entry may be subdivided during disposition pursuant to paragraph (a)(2) of this section, except that removal and destruction of any damaged or otherwise unsound product from a lot destined for reexportation is permitted under supervision of USDA prior to exportation. Additionally, such refused entry lot may not be shipped for export from any port other than that through which the product came into the United States, without the expressed consent of the Administrator based on full information concerning the product's disposition, including the name of the vessel and the date of export. For the purposes of this paragraph, the term ''lot'' shall refer to that product indentified on MP Form 410 in the original request for inspection for importation pursuant to § 327.5.

(4) Product which has been refused entry solely because of misbranding, in lieu of exportation or destruction pursuant to paragraph (a)(2) of this section, may be brought into compliance with the requirements of this part, under supervision of an authorized representative of the Administrator.

(5) The owner or consignee shall have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in paragraph (a)(2) of this section for ''refused entry'' product. Extension beyond the 45-day period may

be granted by the Administrator when extreme circumstances warrant it; e.g., a dock workers' strike or an unforeseeable vessel delay.

(6) If the owner or consignee fails to take the required action within the time specified under paragraph (a)(5) of this section, the Department will take such action as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expense in the appropriate legal forum.

(7) No product which has been refused entry and exported to another country pursuant to paragraph (a)(2) of this section may be returned to the United States under any circumstance. Any such product so returned to the United States shall be subject to administrative detention in accordance with section 402 of the Act and seizure and condemnation in accordance with section 403 of the Act.

(b) Upon the request of the Director of Customs at the port where a product is offered for clearance through the customs, the consignee of the product shall, at the consignee's own expense, immediately return to the Director any product which has been delivered to consignee under § 327.7 and subsequently designated ''U.S. Refused Entry'' or found in any respect not to comply with the requirements in this part.

(c) All charges for storage, cartage, and labor with respect to any product which was imported contrary to the Act shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such product and any other product thereafter imported by or for such owner or consignee.

[35 FR 15610, Oct. 3, 1970, as amended at 48 FR 15889, Apr. 13, 1983; 49 FR 29568, July 23, 1984; 50 FR 19907, May 13, 1985; 53 FR 17015, May 13, 1988; 54 FR 50735, Dec. 11, 1989]

§ 327.14 Marking of products and labeling of immediate containers thereof for importation.

(a) Product which is offered for importation, and which is susceptible of marking, shall, whether or not enclosed in an immediate container, bear the name of the country of origin, preceded by the words ''product of''; the establishment number assigned by the foreign meat inspection system and certified to the Program; and such other markings as are necessary for compliance with part 316 of this subchapter. When such markings are imprints of stamps or brands made with branding ink, such ink shall be harmless and shall create permanent imprints. In case the name of the country of origin appears as part of an official mark of the national foreign government and such name is prominently and legibly displayed, the words ''product of'' may be omitted.

(b) In addition to the marking of products required under paragraph (a) of this section, the immediate container of any product offered for importation:

(1) Shall bear a label showing in accordance with § 317.2 of this subchapter all information required by that section (except that the establishment number assigned by the foreign meat inspection system and certified to the Program and the official inspection mark of the foreign meat inspection system shall be shown instead of the official inspection legend of the United States) and in addition the name of the country of origin preceded by the words ''product of,'' immediately under the name or descriptive designation of the product as required by § 317.2: *Provided,* That such establishment number may be omitted from a label lithographed directly on a can if said number is lithographed or embossed elsewhere on the can; and

(2) Shall, if such immediate container is a sealed metal container, have the establishment number assigned by the foreign meat inspection authority and certified by the Program embossed or lithographed on the sealed metal container, and such establishment number shall not be covered or obscured by any label or other means.

(c) All marks and other labeling for use on or with immediate containers, as well as private brands on carcasses or parts of carcasses, must be approved by the Food Safety and Inspection Service in accordance with part 412 of this chapter before products bearing such marks, labeling, or brands will be entered into the United States. The

marks of inspection of foreign systems embossed on metal containers or branded on carcasses or parts thereof need not be submitted to the Food Safety and Inspection Service for approval, and such marks of inspection put on stencils, box dies, labels, and brands may be used on such immediate containers as tierces, barrels, drums, boxes, crates, and large-size fiberboard containers of foreign products without such marks of inspection being submitted for approval, provided the markings made by such articles are applicable to the product and are not false or misleading.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986; 60 FR 67456, Dec. 29, 1995; 78 FR 66837, Nov. 7, 2013]

§ 327.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

(a) The outside container in which any immediate container of foreign product is shipped to the United States shall bear, in English, in a prominent and legible manner:

(1) The name or descriptive designation of the product in accordance with § 317.2 of this subchapter;

(2) The name of the country of origin; and

(3) The establishment number assigned by the foreign meat inspection system and certified to the Program.

(b) All labeling used with an outside container of foreign product must be approved in accordance with part 317 of this subchapter.

(c) Except for product offered for entry from Canada, all outside containers of products which have been inspected and passed in accordance with this part shall be marked by a Program import inspector or under a Program import inspector's supervision with the official import meat inspection mark prescribed in § 327.26.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986; 54 FR 41048, Oct. 5, 1989]

§ 327.16 Small importations for importer's own consumption; requirements.

Any product in a quantity of 50 pounds or less which was purchased by the importer outside the United States for his/her own consumption, is eligible to be imported into the United States from any country without compliance with the provisions in other sections of this part but subject to applicable requirements under other laws, including the regulations in part 94 of this title. However, Program employees may inspect any product imported under this section to determine whether it is within the class eligible to be imported under this paragraph.

[54 FR 41048, Oct. 5, 1989]

§ 327.17 Returned U.S. inspected and marked products.

U.S. inspected and passed and so marked products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification to and approval of the Deputy Administrator, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, in specific cases.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986]

§ 327.18 Products offered for entry and entered to be handled and transported as domestic; exception.

(a) All products, after entry into the United States, shall be deemed and treated as domestic products and shall be subject to the applicable provisions of the Act and the regulations in this subchapter and the applicable requirements under the Federal Food, Drug and Cosmetic Act, except that products imported under § 327.16 are required to comply only with the requirements of that Act and § 327.16 of this subchapter.

(b) Products entered in accordance with this part may, subject to the provisions of part 318 of this subchapter, be taken into official establishments and be mixed with or added to any product in such establishments which has been inspected and passed therein.

(c) Imported product which has been inspected, passed, and marked under this part may be transported in the course of importation or subsequently

in commerce only upon compliance with part 325 of this subchapter.

[35 FR 15610, Oct. 3, 1970, as amended at 41 FR 18089, Apr. 30, 1976; 54 FR 41049, Oct. 5, 1989]

§ 327.19 Specimens for laboratory examination and similar purposes.

The provisions in this part do not apply to specimens of products for laboratory examination, research, or similar purposes when authorized importation by the Administrator under conditions specified by him in specific cases, including requirements of denaturing or other identification to deter their use for human food. Authorization will not be given for the importation of any products contrary to the provisions of part 94 of this chapter.

§ 327.20 Importation of foreign inedible fats.

No inedible grease, inedible tallow, or other inedible rendered fat shall be imported into the United States unless it has been first denatured as prescribed in § 327.25 of this part and the containers marked as prescribed by § 316.15 of this subchapter or unless it is identified and handled as prescribed by § 325.11 (b) or (c) of this subchapter.

[54 FR 41049, Oct. 5, 1989]

§ 327.21 Inspection procedures for chilled fresh and frozen boneless manufacturing meat.

(a) *Definitions; sampling; standards.* (1) Frozen boneless manufacturing meat is meat, frozen in the fresh state from cattle, sheep, swine, goats, horses, mules, or other equines that has all bone removed and is cut into pieces or trimmings, frozen into a compact block of any shape and suitable for slicing or chopping in the manufacturing of meat food products. As used in this section, the term ''frozen'' includes ''chilled fresh,'' and ''lot'' means any amount of frozen boneless manufacturing meat of one species, similarly packaged, shipped from one establishment, and offered for import inspection under one or more foreign inspection certificates.

(2) Imported frozen boneless manufacturing meat shall be sampled as required by § 327.6(a) of this part, and the samples defrosted for inspection. The Program import inspector, or in the case of Canadian product subject to procedures described in § 327.5(d)(1), the Canadian representative will select from a lot the appropriate number of cartons specified by the table of sampling plans. The total sample for inspection will consist of the necessary number of 12-pound units drawn from these cartons. The 12-pound units selected will be completely defrosted and examined.

(b) *Lots refused entry.* Reinspection (including resampling) will be provided for any lot of frozen boneless manufacturing meat which was refused entry under this section on the basis of the original evaluation of the sample thereof, upon appeal from the inspector's initial decision.

[35 FR 15610, Oct. 3, 1970, as amended at 49 FR 36819, Sept. 20, 1984; 51 FR 44901, Dec. 15, 1986; 54 FR 275, Jan. 5, 1989; 57 FR 27906, June 23, 1992]

§ 327.22 [Reserved]

§ 327.23 Compliance procedure for cured pork products offered for entry.

(a) *Definitions.* For the purposes of this section:

(1) A *Product* is that cured pork article which is contained within one Group as defined in paragraph (a)(2) of this section and which purports to meet the criteria for a single product designated under the heading ''Product Name and Qualifying Statements'' in the chart in § 319.104 or § 319.105 of this subchapter.

(2) A *Product Group* or a *Group* means one of the following:

(i) Group I, consisting of cured pork products which have been cooked while imperviously encased. Any product that fits into the Group shall be placed in this Group regardless of any other considerations.

(ii) Group II, consisting of cured pork products which have been water cooked. Any product that does not fit into Group I but does fit into Group II shall be placed into Group II regardless of any other considerations.

(iii) Group III, consisting of boneless, smokehouse heated cured pork products. Any boneless product that does not fit into Group I or II shall be placed in Group III.

(iv) Group IV, consisting of bone-in or semi-boneless smokehouse heated cured pork products. Any product that is not completely boneless or still contains all the bone which is traditional for bone-in product and does not fit into Group I, II, or III shall be placed in this Group.

(3) *Protein Fat-Free Percentage, Protein Fat-Free Content, PFF Percentage, PFF Content or PFF* of a product means the meat protein (indigenous to the raw, unprocessed pork cut) content expressed as a percent of the non-fat portion of the finished product.

(4) A *PFF Standardized Difference* is the PFF of the sample minus the minimum PFF requirement, set forth in §319.104 and §319.105 of this subchapter, for the product being analyzed, divided by the Appropriate Standard Deviation for the product group.

(5) The *Absolute Minimum PFF Requirement* is that no laboratory result of an individual sample for PFF content be below the applicable minimum requirement of §319.104 or §319.105 of this subchapter by 2.3 or more percentage points for a Group I or II product or 2.7 or more percentage points for a Group III or IV product.

(6) A *PFF Standardized Arithmetic Average of the Country's Products* is the arithmetic average of PFF Standardized Differences from either 36 or 100 consecutively sampled lots of product entering the United States from a given producing country.

(7) A *PFF Standardized Weighted Average of the Country's Products* is an estimate of the average of the PFF Standardized Differences from either 36 or 100 consecutively sampled lots, adjusted for the size of the lot, of different types of cured pork product entering the United States from a given producing country. A Standardized Weighted Average is computed by multiplying the PFF Standardized Difference calculated for each lot by the number of pounds of product in each lot, adding those results together, and dividing the sum by the total weight of product from all the lots making up the average.

(8) The *Appropriate Standard Deviation* is based on within lot variability. That assigned to Groups I and II = 0.75 percent PFF and that assigned to Groups III and IV = 0.91 percent PFF.

(9) A *Lot* is all product of one type from one establishment presented by an importer as the unit for inspection at the Port of Entry.

(b) *Normal monitoring procedures.* Except for product imported from Canada, the Department shall collect sample(s) of cured pork product on a random basis from lots offered for entry at the Port of Entry and, after analyzing the sample for fat and indigenous protein content, calculate the PFF percentage. The product shall not be held pending laboratory results during the monitoring phase. The PFF percentage for each sample shall be considered along with the cumulative results of prior samples to assess the effectiveness of a country's overall compliance program and to determine the course of action for subsequent lots of product.

(1) Factors determining whether a country's inspection system is functioning adequately:

(i) The PFF percentage for each sample must not be below the minimum PFF requirement by 2.3 percentage points for cured pork products in Groups I and II or 2.7 percentage points for cured pork products in Groups III and IV.

(ii) Both of the PFF Standardized Averages, Arithmetic and Weighted, for the last 100 consecutive lots of all cured pork products from the country must be equal to or greater than zero. The count for the 100 consecutive lots starts with the lots arriving from that country after April 15, 1985.

(iii) Both of the PFF Standardized Averages, Arithmetic and Weighted, for the last 36 consecutive lots of all cured pork products from the country must be above the lowest 5 percent of the Normal distribution. This minimum value is minus 0.28 (−0.28) for the Arithmetic Average and depends on the production volume for the Weighted Average.

(2) Actions when calculations indicate that processing procedures in a country are out-of-compliance:

(i) If the PFF level of a sample taken during normal monitoring procedures is found to be as low as the Absolute Minimum PFF Requirement, the country of origin shall be notified; the lot

involved shall be retained if still available in an official establishment or subject to detention or other actions pursuant to the Act; and all subsequently presented lots of that cured pork product from the same foreign establishment shall be held under retention until the provisions of paragraph (c) are satisfied.

(ii) If either of the PFF Standardized Averages, Arithmetic or Weighted, for the last 100 consecutive lots falls below zero or either of the PFF Standardized Averages for the last 36 consecutive lots falls below the upper 95 percent of the Normal distribution, all available cured pork product from the foreign country shall be subject to administrative retention and all subsequently presented lots of cured pork product from the foreign country shall be held under retention until the provisions of paragraph (c) are satisfied. The country of origin shall be notified, and shall be subject to other actions pursuant to the Act.

(c) *Retention.* When lots of cured pork product are under retention they shall be refused entry and reexported in accordance with §327.13 of this subchapter unless they can be released in accordance with the provisions of paragraph (c)(1), establishments may be returned to normal monitoring procedures in accordance with paragraph (c)(2), and countries may be returned to normal monitoring procedures in accordance with paragraph (c)(3).

(1) If a lot is subject to retention procedures under this section, the Department shall collect five randomly selected sample units from each lot and determine the PFF of each sample unit. The lot may be released into commerce if:

(i) The average PFF percentage of the five randomly selected sample units is equal to or greater than the applicable minimum PFF percentage required by §319.104 or §319.105 of this subchapter, or

(ii) The product is relabeled under the supervision of a program employee so that it conforms to the provisions of §319.104 or §319.105 of this subchapter.

(2) If product from a foreign establishment is subject to retention procedures under this section, the foreign establishment may be returned to normal monitoring procedures when:

(i) Ten consecutively presented lots of that cured pork product from that establishment have been sampled as provided in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (50 in all) is above the Absolute Minimum PFF Percentage.

(3) If a country is subject to retention procedures under this section, the country shall be returned to normal monitoring procedures when:

(i) Twenty-five consecutively presented lots of cured pork product have been sampled as required in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (125 in all) is above the Absolute Minimum PFF Percentage; and

(iii) Both of the PFF Standardized Averages for 36 consecutive lots are in the required percentage of the Normal distribution; and

(iv) Both of the PFF Standardized Averages for 100 consecutive lots are zero or higher.

(4) The sample units collected under retention procedures as provided in paragraph (c)(2) of this section will not be included in the PFF standardized averages for 36 and 100 consecutive lots.

(d) *Adulterated and Misbranded Products.* Products not meeting specified PFF requirements, determined according to procedures set forth in this section, may be deemed adulterated under section 1(m)(8) of the Act (21 U.S.C. 601(m)(8)) and misbranded under section 1(n) of the Act (21 U.S.C. 601(n)).

(e) Activities requiring additional inspectional supervision, such as relabeling, shall be at the importer's expense. In addition, if the importer wishes, he or she may have samples analyzed at an accredited laboratory.

[50 FR 9792, Mar. 12, 1985, as amended at 54 FR 41049, Oct. 5, 1989]

§ 327.24 Appeals; how made.

Any appeal from a decision of any program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

[51 FR 37707, Oct. 24, 1986, as amended at 60 FR 67456, Dec. 29, 1995]

§ 327.25 Disposition procedures for product condemned or ordered destroyed under import inspection.

(a) Carcasses, parts thereof, meat and meat food products (other than rendered animal fats) that have been treated in accordance with the provisions of this section shall be considered denatured for the purposes of the regulations in this part, except as otherwise provided in part 314 of this subchapter for articles condemned at official establishments or at official import inspection establishments.

(1) The following agents are prescribed for denaturing carcasses, parts thereof, meat or meat food products which are affected with any condition that would result in their condemnation and disposal under part 314 of this subchapter if they were at an official establishment or at an official import inspection establishment: Crude carbolic acid; cresylic disinfectant; a formula consisting of 1 part FD&C green No. 3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or other proprietary substance approved by the Administrator in specific cases.[1]

(2) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and except as provided in paragraphs (a) (3) and (5) of this section, the following agents are prescribed for denaturing other carcasses, parts thereof, meat and meat food products, for which denaturing is required by this part: FD&C green No. 3 coloring; FD&C blue No. 1 coloring; FD&C blue No. 2 coloring; finely powdered charcoal; or other proprietary substance approved by the Administrator in specific cases.[1] Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91).[2]

(3) Tripe may be denatured by dipping it in a 6 percent solution of tannic acid for 1 minute followed by immersion in a water bath, then immersing it for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring.

(4) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard done, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product, may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

(5) Before the denaturing agents are applied to articles in pieces more than 4 inches in diameter, the pieces shall be freely slashed or sectioned. (If the articles are in pieces not more than 4 inches in diameter, slashing or sectioning will not be necessary.) The application of any of the denaturing agents listed in paragraph (a) (1) or (2) of this section to the outer surface of molds or blocks or boneless meat, meat by-products, or meat food products shall not be adequate. The denaturing agent must be mixed intimately with

[1] Information as to approval of any proprietary denaturing substance may be obtained from the Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[2] Copies of MP Form 91 may be obtained, without charge, by writing to the Administrative Operations Branch, Food Safety and Inspection Service, U.S. Department of Agriculture, 123 East Grant Street, Minneapolis, Minnesota 55403. Diagrams 2 and 3 of the Meat Denaturing Guide are for comparison purposes only. The Meat Denaturing Guide has been approved for incorporation by reference by the Director, Office of the Federal Register, and is on file at the Federal Register Library.

all the material to be denatured, and must be applied in such quantity and manner that it cannot easily and readily be removed by washing or soaking. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food.

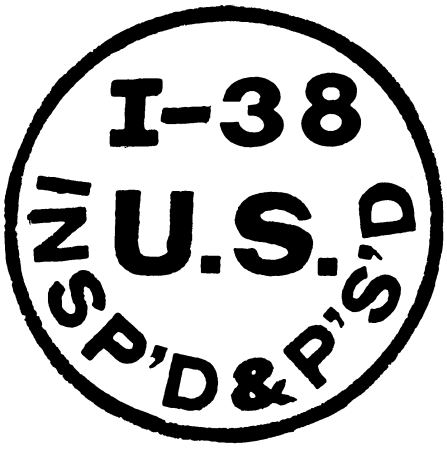
(b) Inedible rendered animal fats shall be denatured by thoroughly mixing therein denaturing oil, No. 2 fuel oil, brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, finely powdered charcoal, or any proprietary denaturing agent approved for the purpose by the Administrator in specific cases. The charcoal shall be used in no less quantity than 100 parts per million and shall be of such character that it will remain suspended indefinitely in the liquid fat. Sufficient of the chosen identifying agents shall be used to give the rendered fat so distinctive a color, odor, or taste that it cannot be confused with an article of human food.

[51 FR 37707, Oct. 24, 1986]

§ 327.26 Official import inspection marks and devices.

(a) When import inspections are performed in official import inspection establishments, the official inspection legend to be applied to imported meat and meat food products shall be in the appropriate form[1] as herein specified.

For application to cattle, sheep, swine, and goat carcasses, primal parts, and cuts, not in containers.

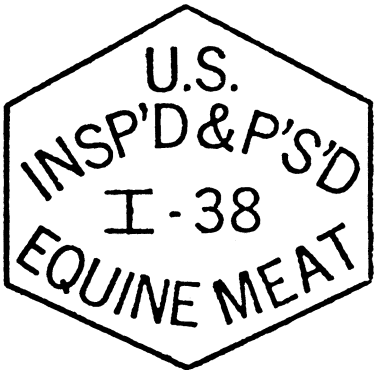


For application to outside containers of meat and meat food products prepared from cattle, sheep, swine, and goats.

For application to horse carcasses, primal parts, and cuts, not in containers.

[1] The number ''I–38'' is given as an example only. The establishment number of the official import inspection establishment where the imported product is inspected shall be used in lieu thereof.

For application to outside containers of horsemeat food products.



For application to mule and other (nonhorse) equine carcasses, primal parts, and cuts, not in containers.

For application to outside containers of equine meat food products.

(b) Except for product offered for entry from Canada, when import inspections are performed in official establishments the official inspection legend to be applied to meat and meat food products offered for entry shall be the appropriate form as specified in §§ 312.2 and 312.3 of this subchapter.

(c) When products are refused entry into the United States, the official mark to be applied to the products refused entry shall be in the following form:

UNITED STATES
REFUSED ENTRY

(d) Devices for applying ''United States Refused Entry'' marks shall be furnished to Program inspectors by the Department.

(e) The ordering and manufacture of brands containing official inspection legends shall be in accordance with the provisions contained in §317.3(c) of the Federal meat inspection regulations.

[51 FR 37708, Oct. 24, 1986, as amended at 54 FR 41049, Oct. 5, 1989]

PART 329—DETENTION; SEIZURE AND CONDEMNATION; CRIMINAL OFFENSES

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15617, Oct. 3, 1970, unless otherwise noted.

§ 329.1 Article or livestock subject to administrative detention.

Any carcass, part of a carcass, meat or meat food product of livestock, or article exempted from the definition of meat food product, or any dead, dying, disabled, or diseased livestock is subject to detention for a period not to exceed 20 days when found by any authorized representative of the Secretary upon any premises where it is held for the purposes of, or during or after distribution in, commerce or it is otherwise subject to Title I or II of the Act, and there is reason to believe that:

(a) Any such article is adulterated or misbranded and is capable of use as human food; or

(b) Any such article has not been inspected, in violation of the provisions of Title I of the Act, any other Federal law, or the laws of any State or Territory, or the District of Columbia; or

(c) Any such article or livestock has been or is intended to be, distributed in violation of the provisions of Title I of the Act, any other Federal law, or the laws of any State or Territory, or the District of Columbia.

§ 329.2 Method of detention; form of detention tag.

An authorized representative of the Secretary shall detain any article or livestock to be detained under this part, by affixing an official ''U.S. Detained'' tag (FSIS Form 8400–2) to such article or livestock.

[55 FR 47842, Nov. 16, 1990]

§ 329.3 Notification of detention to the owner of the article or livestock detained, or the owner's agent, and person having custody.

(a) When any article or livestock is detained under this part, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the article or livestock detained, and

(2) Promptly furnish a copy of a completed ''Notice of Detention'' (FSIS Form 8080–1) to the immediate custodian of the detained article or livestock.

(b) If the owner of the detained article or livestock, or the owner's agent, is not the immediate custodian at the time of detention and if the owner, or owner's agent, can be ascertained and notified, an authorized representative of the Secretary shall furnish a copy of the completed ''Notice of Detention'' to the owner or the owner's agent. Such copy shall be served, as soon as possible, by delivering the notification to the owner, or the owner's agent, or by certifying and mailing the notification to the owner, or the owner's agent, at his or her last known residence or principal office or place of business.

[55 FR 47842, Nov. 16, 1990]

§ 329.4 Notification of governmental authorities having jurisdiction over article or livestock detained; form of written notification.

Within 48 hours after the detention of any livestock or article pursuant to this part, an authorized representative of the Secretary shall give oral or written notification of such detention to any Federal authorities not connected with the Program, and any State or other governmental authorities, having jurisdiction over such livestock or article. In the event notification is given orally, it shall be confirmed in writing, as promptly as circumstances permit.

§ 329.5 Movement of article or livestock detained; removal of official marks.

(a) No article or livestock detained in accordance with the provisions in this part shall be moved by any person from the place at which it is located when so detained, until released by an authorized representative of the Secretary: *Provided,* That any such article or livestock may be moved from the place at which it is located when so detained, for refrigeration, freezing, or storage purposes if such movement has been approved by an authorized representative of the Secretary: *And provided further,* That the article or livestock so moved will be detained by an authorized representative of the Secretary after such movement until such time as the detention is terminated.

(b) Upon terminating the detention of such article or livestock, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the released article or livestock, and

(2) Furnish copies of a completed ''Notice of Termination of Detention'' (FSIS Form 8400–1) to the persons notified when the article or livestock was detained. The notice shall be served by either delivering the notice to such persons or by certifying and mailing the notice to such persons at their last known residences or principal offices or places of business.

(c) All official marks may be required by such representative to be removed from such article or livestock before it is released unless it appears to the satisfaction of the representative that the article or livestock is eligible to retain such marks.

[35 FR 15617, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971; 39 FR 36000, Oct. 7, 1974; 55 FR 47842, Nov. 16, 1990]

§ 329.6 Articles or livestock subject to judicial seizure and condemnation.

Any carcass, part of a carcass, meat or meat food product, or any dead, dying, disabled, or diseased livestock, that is being transported in commerce or is otherwise subject to Title I or II of the Act, or is held for sale in the United States after such transportation, is subject to seizure and condemnation, in a judicial proceeding pursuant to section 403 of the Act if such article or livestock:

(a) Is or has been prepared, sold, transported, or otherwise distributed or offered or received for distribution in violation of the Act, or

(b) Is capable of use as human food and is adulterated or misbranded, or

(c) In any other way is in violation of the Act.

§ 329.7 Procedure for seizure, condemnation, and disposition.

Any article or livestock subject to seizure and condemnation under this part shall be liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any United States district court, or other proper court specified in section 404 of the Act, within the jurisdiction of which the article or livestock is found.

§ 329.8 Authority for condemnation or seizure under other provisions of law.

The provisions of this part relating to seizure, condemnation and disposition of articles or livestock do not derogate from authority for condemnation or seizure conferred by other provisions of the Act, or other laws.

§ 329.9 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to bribery of Program employees, receipt of gifts by Program employees, and forcible assaults on, or other interference with, Program employees while engaged in, or on account of, the performance of their official duties under the Act.

PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 19667, Dec. 29, 1970, unless otherwise noted.

§ 331.1 Definition of "State".

For purposes of this part, the term ''State'' means any State (including the Commonwealth of Puerto Rico) or organized Territory.

§ 331.2 Designation of States under paragraph 301(c) of the Act.

Each of the following States has been designated, under paragraph 301(c) of the Act, as a State in which the provisions of Titles I and IV of the Act shall apply to operations and transactions wholly within such State. The Federal provisions apply, effective on the dates shown below:

State	Effective date of application of Federal provisions
Alaska	July 31, 1999.
Arkansas	June 1, 1981.
California	Apr. 1, 1976.
Colorado	July 1, 1975.
Connecticut	Oct. 1, 1975.
Florida	Dec. 2, 1997.
Guam	Jan. 21, 1972.
Hawaii	Nov. 1, 1995.
Idaho	July 1, 1981.
Kentucky	Jan. 14, 1972.
Maryland	Mar. 31, 1991
Massachusetts	Jan. 12, 1976.
Michigan	Oct. 3, 1981.
Nebraska	Oct. 1, 1971.
Nevada	July 1, 1973.
New Hampshire	Aug. 6, 1978.
New Jersey	July 1, 1975.
New Mexico	Aug. 13, 2007.
New York	July 16, 1975.
Northern Mariana Islands	Oct. 29, 1979.
Oregon	July 1, 1972.
Pennsylvania	July 17, 1972.
Puerto Rico	June 18, 1971.
Rhode Island	Oct. 1, 1981.
Tennessee	Oct. 1, 1975.
Virgin Islands of the U.S	Nov. 27, 1971.
Washington	June 1, 1973.

[35 FR 19667, Dec. 29, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 331.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 331.3 States designated under paragraph 301(c) of the Act; application of regulations.

The provisions of the regulations in this subchapter apply to operations and transactions wholly within each State designated in § 331.2 under paragraph 301(c) of the Act, except as otherwise provided in this section. (The provisions of the regulations apply in all respects to operations and transactions in or for commerce.)

(a) Each establishment located in such a designated State shall be granted inspection required under § 302.1(a)(2) of this subchapter only if it is found, upon a combined evaluation of its premises, facilities, and operating procedures, to be capable of producing products that are not adulterated or misbranded.

(b) Section 305.2 of this subchapter will apply to establishments required to have inspection under § 302.1(a)(2) of this subchapter, except that existing interconnections between official and unofficial establishments will be permitted if it is determined in specific cases that the interconnections are such that transfer of inedible product into the official establishment would be difficult or unusual, and any such transfers are strictly prohibited, except as permitted under other provisions of this subchapter. It is essential that separation of facilities be maintained to the extent necessary to assure that inedible product does not enter the official establishment contrary to the regulations in this subchapter.

(c) Sections 416.2(c), (d), (e), (f), and (h) of this chapter shall apply to such establishments.

(d) Section 314.2 of this subchapter shall apply to such establishments, except that a separate room or compartment need not be provided for inedible products if they can be handled so that they do not create insanitary conditions in any room or compartment used for edible products or otherwise render any edible products adulterated and do not interfere with the conduct of inspection. For example, intestines, paunch contents, feet, and hides might be accumulated on the kill floor in clean, watertight drums with close fitting covers if there is sufficient space to store them out of the way until the close of the day's operation.

(e) Sections 316.7, 317.3, and 412.1 of this chapter apply to such establishments, except as provided in this paragraph (e).

(1) The operator of each such establishment will, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use, (upon the date of inauguration of inspection) to the Front Line Supervisor of the circuit in which the establishment is located. Temporary approval, pending formal approval under §§ 316.7, 317.3, and 412.1 of this chapter, will be granted by the Front Line Supervisor for labeling and

marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by section 1(n) of the Act.

(2) The circuit supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the Washington, DC, office of the Labeling and Packaging Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Front Line Supervisor (showing any modifications required by the Front Line Supervisor) to the FSIS Labeling and Program Delivery Staff, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Front Line Supervisor must receive approval as required by §§ 316.7, 317.3, and 412.1 of this chapter, or their use must be discontinued.

(4) The circuit supervisor will also review all shipping containers to insure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of self-destructive pressure sensitive tape or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of this subchapter must be destroyed or removed from the official establishment.

(f) Sections 320.1, 320.2, 320.3, 320.4, 320.5, 325.20, and 325.21 apply to operations and transactions not in or for commerce in a State designated under paragraph 301(c) only if the State is also designated under section 205 of the Act and if such provisions are applicable as shown in § 331.6.

(g) Section 321.1(a) of this subchapter will not apply to States designated under paragraph 301(c) of the Act.

(h) Parts 322 and 327 and § 325.3 of this subchapter relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

(i) Part 325 of this subchapter will apply to establishments required to have inspection under § 302.1(a)(2) of this subchapter and to operations and transactions solely in or for intrastate commerce, except as provided in paragraphs (h) and (j) of this section.

(j) Sections 325.4, 325.15, and 325.1(b) of this subchapter will not apply to require a certificate, or evidence thereof, for the distribution solely within any designated State of products that are U.S. inspected and passed and so marked.

[35 FR 19667, Dec. 29, 1970, as amended at 36 FR 12004, June 24, 1971; 41 FR 18089, Apr. 30, 1976; 62 FR 45026, Aug. 25, 1997; 64 FR 56416, Oct. 20, 1999; 78 FR 66837, Nov. 7, 2013]

§ 331.4 Control and disposal of non-federally-inspected products in States designated under paragraph 301(c) of the Act.

Upon the effective date of designation of a State under paragraph 301(c) of the Act, no products can be prepared within the State unless they are prepared under inspection pursuant to the regulations in this subchapter or are exempted from the requirement of inspection under § 303.1 of this subchapter, and no unexempted products which were prepared without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, products which were prepared and inspected and passed under the supervision of a responsible State or local inspection agency can be distributed solely within the State, provided they are not adulterated or misbranded, except that the official inspection legend is not required. Within the 90-day period, products that have

been inspected by the State or local inspection agency may be further prepared and otherwise handled in official establishments required to have inspection under § 302.1(a)(2) of this subchapter or at establishments exempted from the requirements of such inspection under § 303.1 of this subchapter, and may be distributed as provided in this section but otherwise shall be handled in accordance with § 305.4 of this subchapter. Such products shall not bear any [Federal] official inspection legends. After said 90–day period, only federally inspected and passed products may be distributed within the designated State, except as provided in § 303.1 of this subchapter.

§ 331.5 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of products; application of regulations.

(a) An establishment preparing products solely for distribution within any State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

(1) Any meat or meat food product prepared at the establishment is adulterated in any of the following respects:

(i) It bears or contains a pesticide chemical, food additive, or color additive, that is ''unsafe'' within the meaning of sections 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act or was intentionally subjected to radiation in a manner not permitted under section 409 of said Act; or if it bears or contains any other added poisonous or added deleterious substance which may render it injurious to health or make it unfit for human food; or

(ii) It consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, or unwholesome or otherwise unfit for human food (for example, it was prepared from meat or other ingredients exhibiting spoilage characteristics; or it is, or was prepared from, a carcass affected with a disease transmissible to humans and its condemnation would be required under part 309 or 310 of the Federal Meat Inspection regulations (9 CFR parts 309, 310) at federally inspected establishments; or

(iii) It has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (for example if insects or vermin are not effectively controlled at the establishments, or insanitary water is used in preparing meat or meat food products for human food); or

(iv) It is, in whole or in part, the product of an animal that died otherwise than by slaughter; or

(v) Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; and

(2) Such adulterated articles are intended to be or are distributed from the establishment while capable of use as human food.

(b) When any such establishment is identified by a Program Inspector as one producing adulterated product, which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:

(1) The Program Inspector will informally advise the operator of the establishment concerning the deficiencies found by him and report his findings to the appropriate Regional Director for the Program. When it is determined by the Regional Director that any establishment preparing products solely for distribution within any State is producing adulterated products for distribution within such State which would clearly endanger the public health, written notification thereof will be issued to the appropriate State officials, including the Governor of the State and the appropriate Advisory Committee, for effective action under State or local law to prevent such endangering of the public health. Such written notification shall clearly specify the deficiencies deemed to result in the production of adulterated products and shall specify a reasonable time for such action under State or local law.

(2) If effective action is not taken under State or local law within the specified time, written notification

shall be issued by the Regional Director to the operator of the establishment, specifying the deficiencies involved and allowing him ten days to present his views or make the necessary corrections, and notifying him that failure to correct such deficiencies may result in designation of the establishment and operator thereof as subject to the provisions of titles I and IV of the Act as though engaged in commerce.

(3) Thereafter the Program Inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated products, which would clearly endanger the public health, and formal notice of such designation will be issued to the operator of the establishment by the Regional Director.

(c) Products on hand at the time of designation of an establishment under this section are subject to detention, seizure and condemnation in accordance with part 329 of this subchapter: *Provided*, That products that have been federally inspected and so identified and that have not been further prepared at any nonfederally inspected establishment may be released for distribution if the products appear to be not adulterated or misbranded at the time of such release.

(d) No establishment designated under this section can lawfully prepare any products unless it first obtains inspection or qualifies for exemption under § 303.1 of this subchapter. All of the provisions of the regulations shall apply to establishments designated under this section, except that the exceptions provided for in § 331.3 of this part shall apply to such establishments.

[35 FR 19667, Dec. 29, 1970, as amended at 83 FR 25308, May 31, 2018]

§ 331.6 Designation of States under section 205 of the Act; application of sections of the Act and the regulations.

Each of the following States has been designated, effective on the date shown below, under section 205 of the Act, as a State in which the provisions of the sections of the Act and regulations specified below shall apply to operators engaged, other than in or for commerce, in the kinds of business indicated below:

Sections of act and regulations	Classes of operators	State	Effective date of designation
Act, section 202; §§ 320.1, 320.2, 320.3, and 320.4.	Persons engaged (not in or for commerce) in (1) the business of slaughtering any livestock or preparing, freezing, packaging or labeling any livestock carcasses or parts or products thereof, for use as human food or animal food; (2) the business of buying or selling (as a meat broker, wholesaler, or otherwise), transporting or storing any livestock carcasses or parts or products thereof; or (3) business as a renderer, or in the business of buying, selling, or transporting any dead, dying, disabled, or diseased livestock or parts of carcasses of any livestock that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Mar. 29, 1982.
		California	Apr. 1, 1976.
		Colorado	July 1, 1975.
		Connecticut	Oct. 1, 1975.
		Guam	Nov. 19, 1976.
		Idaho	Mar. 29, 1982.
		Kentucky	Apr. 18, 1973.
		Maryland	Mar. 31, 1991.
		Massachusetts	Jan. 12, 1976.
		Michigan	Mar. 29, 1982.
		Nebraska	Jan. 31, 1975.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1975.
		Northern Mariana Islands.	Oct. 29, 1979.
		Oregon	Jan. 31, 1975.
		Pennsylvania	May 2, 1974.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		Tennessee	Oct. 1, 1975.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.

Sections of act and regulations	Classes of operators	State	Effective date of designation
Act, 203; § 320.5	Persons engaged (not in or for commerce) in business as a meat broker; renderer; animal food manufacturer; wholesaler or public warehouseman of livestock carcasses, or parts or products thereof; or buying, selling, or transporting any dead, dying, disabled, or diseased livestock, or parts of carcasses of any such livestock that dies otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Mar. 29, 1982.
		California	Apr. 1, 1976.
		Colorado	July 1, 1975.
		Connecticut	Oct. 1, 1973.
		Guam	Nov. 19, 1976.
		Idaho	Mar. 29, 1982.
		Kentucky	Apr. 18, 1976.
		Maryland	Mar. 31, 1991.
		Massachusetts	Jan. 12, 1975.
		Michigan	Mar. 29, 1982.
		Nebraska	Jan. 31, 1975.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1973.
		Northern Mariana Islands.	Oct. 29, 1979.
		Oregon	Jan. 31, 1974.
		Pennsylvania	May 2, 1975.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		Tennessee	Oct. 1, 1975.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.
Act, 204; §§ 325.20 and 325.21.	Persons engaged (not in or for commerce) in the business of buying, selling or transporting any dead, dying, disabled or diseased animals, or parts of carcasses of any animals that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Mar. 29, 1982.
		Connecticut	Oct. 1, 1975.
		Guam	Nov. 19, 1976.
		Idaho	Mar. 29, 1982.
		Kentucky	Apr. 18, 1973.
		Maryland	Mar. 31, 1991.
		Massachusetts	Jan. 12, 1976.
		Michigan	Mar. 29, 1982.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1975.
		Northern Mariana Islands.	Oct. 29, 1979.
		Oregon	Jan. 31, 1975.
		Pennsylvania	May 2, 1974.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.

[35 FR 19667, Dec. 29, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 331.6, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

PART 332—SELECTED ESTABLISHMENTS; COOPERATIVE PROGRAM FOR INTERSTATE SHIPMENT OF CARCASSES, PARTS OF CARCASSES, MEAT, AND MEAT FOOD PRODUCTS

Sec.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 76 FR 24753, May 2, 2011, unless otherwise noted.

§ 332.1 Definitions.

Cooperative interstate shipment program. A cooperative meat inspection program described in § 321.3 of this subchapter.

Cooperative State meat inspection program. A cooperative State-Federal meat inspection program described in § 321.1 of this subchapter.

Designated personnel. State inspection personnel that have been trained in the enforcement of the Act and any additional State program requirements in order to provide inspection services to selected establishments.

Interstate commerce. ''Interstate commerce'' has the same meaning as ''commerce'' under § 301.2 of this subchapter.

Selected establishment. An establishment operating under a State cooperative meat inspection program that has been selected by the Administrator, in coordination with the State where the establishment is located, to participate in a cooperative interstate shipment program.

§ 332.2 Purpose.

This part prescribes the conditions under which States that administer cooperative State meat inspection programs and establishments that operate under such programs may participate in a cooperative interstate shipment program.

§ 332.3 Requirements for establishments; ineligible establishments.

(a) An establishment that operates under a cooperative State meat inspection program may apply to participate in a cooperative interstate shipment program under this part if:

(1) The establishment employs on average no more than 25 employees based on the standards described in paragraph (b) of this section, or

(2) The establishment employed more than 25 employees but fewer than 35 employees as of June 18, 2008. If selected to participate in a cooperative interstate shipment program, an establishment under this paragraph must employ on average no more than 25 employees as of July 1, 2014, or it must transition to become an official establishment as provided in § 332.11 of this part.

(b) An establishment that has 25 or fewer employees based on the following standards is considered to have 25 or fewer employees on average for purposes of this part.

(1) All individuals, both supervisory and non-supervisory, employed by the establishment on a full-time, part-time, or temporary basis whose duties involve handling the meat or meat food products prepared by the establishment are counted when calculating the total number of employees.

(2) All individuals employed by the establishment from a temporary employee agency, professional employee organization, or leasing concern whose duties involve handling the meat or meat food products prepared by the establishment are counted when calculating the total number of employees.

(3) The average number of employees is calculated for each of the pay periods for the preceding 12 calendar months.

(4) Part-time and temporary employees are counted the same as full-time employees.

(5) If the establishment has not been in business for 12 months, the average number of employees is calculated for each of the pay periods in which the establishment has been in business.

(6) Volunteers who receive no compensation are not considered employees unless their duties involve handling the meat or meat food products prepared by the establishment.

(7) The total number of employees can never exceed 35 individuals at any given time, regardless of the average number of employees.

(c) The following establishments are ineligible to participate in a cooperative interstate shipment program:

(1) Establishments that employ more than 25 employees on average (except as provided under paragraph (a)(2) of this section);

(2) Establishments operating under a Federal-State program as provided in

§ 321.2 of this subchapter as of June 18, 2008;

(3) Official establishments;

(4) Establishments that were official establishments as of June 18, 2008, but that were re-organized on a later date by the person that controlled the establishment as of June 18, 2008;

(5) Establishments operating under a cooperative State meat inspection that employed more than 35 employees as of June 18, 2008, that were reorganized on a later date by the person that controlled the establishment as of June 18, 2008;

(6) Establishments that are the subject of a transition under § 332.11 of this part;

(7) Establishments that are in violation of the Act;

(8) Establishments located in States without a cooperative State meat inspection program; and

(9) Establishments located in a State whose agreement for a cooperative interstate shipment program was terminated by the Administrator as provided in § 321.3(d) of this subchapter.

(d) An establishment that meets the conditions in paragraph (a) of this section and that is not an ineligible establishment under paragraph (c) of this section may apply for selection into a cooperative interstate shipment program through the State in which the establishment is located.

[76 FR 24753, May 2, 2011; 76 FR 81360, Dec. 28, 2011]

§ 332.4 State request for cooperative agreement.

(a) State participation in a cooperative interstate shipment program under this part is limited to States that have implemented cooperative State meat inspection programs.

(b) To request an agreement for a cooperative interstate shipment program under this part, a State must submit a written request to the Administrator through the FSIS District Office for the FSIS District in which the State is located. In the request the State must:

(1) Identify establishments in the State that have requested to be selected for the program that the State recommends for initial selection into the program, if any;

(2) Demonstrate that the State is able to provide the necessary inspection services to selected establishments in the State and conduct any related activities that would be required under a cooperative interstate shipment program established under this part; and

(3) Agree that, if the State enters into an agreement with FSIS for a cooperative interstate shipment program, the State will:

(i) Provide FSIS with access to the results of all laboratory analyses conducted on product samples from selected establishments in the State;

(ii) Notify the selected establishment coordinator for the State of the results of any laboratory analyses that indicate that a product prepared in a selected establishment may be adulterated or may otherwise present a food safety concern; and

(iii) When necessary, cooperate with FSIS to transition selected establishments in the State that have been deselected from a cooperative interstate shipment program to become official establishments.

(c) If the Administrator determines that a State that has submitted a request to participate in a cooperative interstate shipment program qualifies to enter into a cooperative agreement for such a program, the Administrator and the State will sign a cooperative agreement that sets forth the terms and conditions under which each party will cooperate to provide inspection services to selected establishments located in the State.

(d) After the Administrator and a State have signed an agreement for a cooperative interstate shipment program as provided in paragraph (c) of this section, the Administrator will:

(1) Appoint an FSIS employee as the FSIS selected establishment coordinator for the State and

(2) Coordinate with the State to select establishments to participate in the program as provided in § 332.5(b) of this part.

§ 332.5 Establishment selection; official number for selected establishments.

(a) An establishment operating under a cooperative State meat inspection program will qualify for selection into

a cooperative interstate shipment program if the establishment:

(1) Has submitted a request to the State to be selected for the program;

(2) Has the appropriate number of employees under § 332.3(a) of this part;

(3) Is not ineligible to participate in a cooperative interstate shipment program under § 332.3(c) of this part;

(4) Is in compliance with all requirements under the cooperative State meat inspection program; and

(5) Is in compliance with all requirements under the Act and the implementing regulations in this chapter.

(b) To participate in a cooperative interstate shipment program, an establishment that meets the conditions in paragraph (a) of this section must be selected by the Administrator, in coordination with the State where the establishment is located.

(c) If an establishment is selected to participate in a cooperative interstate shipment program as provided in paragraph (b) of this section, the State is to assign the establishment an official number that reflects the establishment's participation in the cooperative interstate shipment program and advise the FSIS selected establishment coordinator for the State of the official number assigned to each selected establishment in the State. The official number assigned to every selected establishment must contain a suffix, e.g., ''SE,'' that identifies the establishment as a selected establishment and that identifies the State, e.g., ''SETX,'' for ''selected establishment Texas.''

(d) Failure of the State to comply with paragraph (c) of this section will disqualify the State from participation in the cooperative interstate shipment program.

§ 332.6 Commencement of a cooperative interstate shipment program; inspection by designated personnel and official mark.

(a) A cooperative interstate shipment program will commence when the Administrator, in coordination with the State, has selected establishments in the State to participate in the program.

(b) Inspection services for selected establishments participating in a cooperative interstate shipment program must be provided by designated personnel, who will be under the direct supervision of a State employee.

(c) Carcasses, parts of carcasses, meat, and meat food products prepared in a selected establishment and inspected and passed by designated State personnel must bear an official Federal mark, stamp, tag, or label of inspection in the appropriate form prescribed in part 312 of this subchapter that includes the information specified in § 332.5(c) of this part.

(d) Carcasses, parts of carcasses, meat, and meat food products prepared in a selected establishment that comply with the conditions in paragraph (c) of this section may be distributed in interstate commerce.

§ 332.7 Federal oversight of a cooperative interstate shipment program.

(a) The FSIS selected establishment coordinator for a State that has entered into an agreement for a cooperative interstate shipment program will visit each selected establishment in the State on a regular basis to verify that the establishment is operating in a manner that is consistent with the Act and the implementing regulations in this chapter. The frequency with which the SEC will visit selected establishments under the SEC's jurisdiction will be based on factors that include, but are not limited to, the complexity of the operations conducted at the selected establishment, the establishment's schedule of operations, and the establishment's performance under the cooperative interstate shipment program. If necessary, the selected establishment coordinator, in consultation with the District Manager that covers the State, may designate qualified FSIS personnel to visit a selected establishment on behalf of the selected establishment coordinator.

(b) The selected establishment coordinator, in coordination with the State, will verify that selected establishments in the State are receiving the necessary inspection services from designated personnel, and that these establishments are eligible, and remain eligible, to participate in a cooperative interstate shipment program. The selected establishment coordinator's verification activities may include:

(1) Verifying that each selected establishment employs, and continues to employ, 25 or fewer employees, on average, as required under § 332.3(a) of this part, unless the establishment is transitioning to become an official establishment;

(2) Verifying that the designated personnel are providing inspection services to selected establishments in a manner that complies with the Act and the implementing regulations in this chapter;

(3) Verifying that that the State staffing levels for each selected establishments are appropriate to carry out the required inspection activities; and

(4) Assessing each selected establishment's compliance with the Act and implementing regulations under this chapter.

(c) If the selected establishment coordinator determines that designated personnel are providing inspection services to selected establishments in the State in a manner that is inconsistent with the Act and the implementing regulations in this chapter, the Administrator will provide an opportunity for the State to develop and implement a corrective action plan to address inspection deficiencies identified by the selected establishment coordinator. If the State fails to develop a corrective action plan, or the selected establishment coordinator for the State determines that the corrective action plan is inadequate, the Administrator will terminate the agreement for the cooperative interstate shipment program as provided in § 321.3(d) of this chapter.

§ 332.8 Quarterly reports.

(a) The selected establishment coordinator will prepare a report on a quarterly basis that describes the status of each selected establishment under his or her jurisdiction.

(b) The quarterly report required in paragraph (a) of this section will:

(1) Include the selected establishment coordinator's assessment of the performance of the designated personnel in conducting inspection activities at selected establishments and

(2) Identify those selected establishments that the selected establishment coordinator has verified are in compliance with the Act and implementing regulations in this chapter, those that have been deselected under § 332.10 of this part, and those that are transitioning to become official establishments under § 332.11 of this part.

(c) The selected establishment coordinator is to submit the quarterly report to the Administrator through the District Manager for the State where the selected establishments identified in the report are located.

§ 332.9 Enforcement authority.

(a) To facilitate oversight and enforcement of this part, selected establishments operating under a cooperative interstate shipment program must, upon request, give the FSIS selected establishment coordinator or other FSIS officials access to all establishment records required under the Act and the implementing regulations in this chapter. The Administrator may deselect any selected establishment that refuses to comply with this paragraph.

(b) Selected establishment coordinators may initiate any appropriate enforcement action provided for in part 500 of this chapter if they determine that a selected establishment under their jurisdiction is operating in a manner that is inconsistent with the Act and the implementing regulations in this chapter. Selected establishments participating in a cooperative interstate shipment program are subject to the notification and appeal procedures set out in part 500 of this chapter.

(c) If inspection at a selected establishment is suspended for any of the reasons specified in § 500.3 or § 500.4 of this chapter, FSIS will:

(1) Provide an opportunity for the establishment to implement corrective actions and remain in the cooperative interstate shipment program, or

(2) Move to deselect the establishment as provided in § 332.10 of this part.

(d) The decision to deselect a selected establishment under a suspension will be made on a case-by-case basis. In making this decision, FSIS, in consultation with the State where the selected establishment is located, will consider, among other factors:

(1) The non-compliance that led to the suspension;
(2) The selected establishment's compliance history; and
(3) The corrective actions proposed by the selected establishment.

§ 332.10 Deselection of ineligible establishments.

(a) The Administrator will deselect a selected establishment that becomes ineligible to participate in a cooperative interstate shipment program for any reason listed under § 332.3(c) of this part.
(b) An establishment that has been deselected must transition to become an official establishment as provided in § 332.11 of this part.

§ 332.11 Transition to official establishment.

(a) If an establishment is deselected from a cooperative interstate shipment program as provided in § 332.10 of this part, FSIS, in coordination with the State where the establishment is located, will develop and implement a plan to transition the establishment to become an official establishment. Except that an establishment that was deselected from a cooperative interstate shipment program because it is located in a State whose agreement for such a program was terminated may either transition to become an official establishment or transition to become a State-inspected establishment under the cooperative State meat inspection program.
(b) An establishment that has been deselected from a cooperative interstate shipment program and successfully transitioned to become an official establishment may withdraw from the Federal inspection program and resume operations under the cooperative State meat inspection program after operating as an official establishment in full compliance with the Act for a year.

§ 332.12 Transition grants.

(a) Transition grants are funds that a State participating in a cooperative interstate shipment program under this part may apply for to reimburse selected establishments in the State for the cost to train one individual in the seven HACCP principles for meat or poultry processing as required under § 417.7 of this chapter and associated training in the development of sanitation standard operating procedures required under part 416 of this chapter.
(b) A State participating in a cooperative interstate shipment program that receives a transition grant must use grant funds to reimburse the training costs of one employee per each selected establishment in the State. Any other use of such funds is prohibited.

§ 332.13 Separation of operations.

A selected establishment may conduct operations under the cooperative State meat inspection program if the establishment implements and maintains written procedures for complete physical separation of product and process for each operation by time or space.

§ 332.14 Voluntary withdrawal.

A selected establishment that is in full compliance with the requirements in this part may voluntarily end its participation in a cooperative interstate shipment program and operate under the cooperative State meat inspection program. Establishments that voluntarily end their participation in the cooperative may re-apply for the program after operating under the cooperative State meat inspection program for one year.

PART 335—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE FEDERAL MEAT INSPECTION ACT

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 42 FR 10960, Feb. 25, 1977, unless otherwise noted. Redesignated at 64 FR 66545, Nov. 29, 1999.

Subpart A—Criminal Violations

AUTHORITY: Sec. 406, Pub. L. 99–641, 100 Stat. 3571; 21 U.S.C. 606 note.

§ 335.40 Opportunity for presentation of views before report of criminal violations.

(a) Except as provided in paragraphs (a)(1) through (5) of this section, before

any violation of the Federal Meat Inspection Act is reported to the Department of Justice by the Secretary for criminal prosecution the Secretary must give reasonable notice to the suspected violator that the Secretary intends to report the violation for prosecution and give the suspected violator an opportunity to present the violator's views to the Secretary with respect to such proceeding.

(1) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in the alteration or destruction of evidence, or where disclosure could result in injury to persons or property.

(2) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in flight of a suspected violator to avoid prosecution.

(3) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in compromising special investigative techniques, such as undercover or other covert operations.

(4) Notice and opportunity need not be provided when the impending criminal referral involves suspicion of bribery and related offenses, or clandestine slaughtering and/or processing operations.

(5) Notice and opportunity need not be provided when the impending referral is part of an investigation involving non-Act violations, and the Act and non-Act violations are jointly referred for prosecution.

(b) A notice of opportunity to present views will be sent by registered or certified mail, summarize the violations that constitute the basis of the contemplated prosecution, and describe the procedures for presentation of views. Any information given by a respondent, orally or in writing, shall become part of the Department's official record concerning the matter. The Department is under no obligation to disclose evidence to the suspected violator.

[52 FR 13828, Apr. 27, 1987]

PART 350—SPECIAL SERVICES RELATING TO MEAT AND OTHER PRODUCTS

Sec.

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17, 2.55.

SOURCE: 23 FR 9982, Dec. 23, 1958, unless otherwise noted. Redesignated at 30 FR 4195, Mar. 31, 1965, and further redesignated at 35 FR 15554, Oct. 3, 1970.

§ 350.1 Meaning of words.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 350.2 Definitions.

For the purposes of the regulations in this part, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

(a) *Department*. The United States Department of Agriculture.

(b) *Service*. The Food Safety and Inspection Service of the Department.

(c) *Administrator*. The Administrator of the Service or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(d) [Reserved]

(e) *Inspector*. Any officer or employee of the Department authorized to perform any duties under the regulations in this part.

(f) *Person*. Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other organized group of any of the foregoing.

(g) *Federally inspected and passed*. Inspected and passed under the Meat Inspection Act, as amended (21 U.S.C. 71 *et seq.*) or under the provisions in paragraphs 306 (b) and (c) of the Tariff Act of 1930 (19 U.S.C. 1306 (b) and (c)).

(h) *Official establishment.* An establishment operated under Federal meat inspection pursuant to the Meat Inspection Act, as amended (21 U.S.C. 71 *et seq.*).

(i) *Food article.* Any article of human food derived wholly or in part from meat, meat byproducts, or meat food products, which is not subject to the Federal meat inspection laws, and animal casings, for which the mark of Federal meat inspection is requested: *Provided,* That such articles and casings are derived from federally inspected and passed carcasses.

(j) [Reserved]

(k) *Secretary.* The Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or may hereafter be delegated, to act in his stead in connection with the function involved.

[23 FR 9982, Dec. 23, 1958, as amended at 25 FR 9642, Oct. 7, 1960; 30 FR 258, Jan. 9, 1965. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 6021, Apr. 15, 1967; 32 FR 13115, Sept. 15, 1967. Further redesignated at 35 FR 15554, Oct. 3, 1970, and amended at 43 FR 11147, Mar. 17, 1978; 54 FR 1329, Jan. 13, 1989]

§ 350.3 Types and availability of service.

Upon application in accordance with § 350.5 the following types of service may be furnished under the regulations in this part:

(a) *Identification service.* (1) Meat or other product that is federally inspected and passed at an official establishment, or upon importation, under the meat inspection laws, is officially marked to identify it as federally inspected and passed. In order to facilitate the division of such meat or other product into smaller portions or its combination into larger units and still maintain its identity as product which has been federally inspected and passed and so marked, inspectors may supervise the handling of the product and mark such portions or units with the marks of Federal inspection when they determine that the identity has been maintained.

(2) At the time service is furnished product must be sound, wholesome and fit for human food. The service will be available only on premises other than those of an official establishment. The sanitation of the plant or area where service is furnished must comply with applicable provisions of part 416, §§ 416.1 through 416.6 of this chapter.

(3) The mark of inspection shall be applied only under the immediate supervision of an inspector.

(4) The service will be available for products moved in tank cars and tank trucks from an official establishment or from a location operating under this service only if such tank cars or tank trucks bear a label before leaving such official establishment or such other location, in accordance with 9 CFR §§ 316.14 and 317.2.

(b) *Certification service.* At the request of a purchaser, supplier, exporter, or others, inspectors may make certification regarding livestock products for human food purposes (including casings), to be exported, as meeting conditions or standards that are not imposed or are in addition to those imposed by the regulations in parts 301 through 331 of this chapter and the laws under which such regulations were issued.

(c) *Food inspection service.* An inspection and certification service for wholesomeness relating to the manufacture of a food article may be furnished upon application. All applicable provisions of this chapter shall apply to the preparation, labeling and certification of the food article prepared under this food inspection service.

(d) [Reserved]

[25 FR 9642, Oct. 7, 1960, as amended at 30 FR 258, Jan. 9, 1965. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 30 FR 8675, July 9, 1965. Further redesignated at 35 FR 15554, Oct. 3, 1970, and amended at 38 FR 29215, Oct. 23, 1973; 53 FR 28634, July 29, 1988; 54 FR 1329, Jan. 13, 1989; 64 FR 56416, Oct. 20, 1999; 65 FR 2284, Jan. 14, 2000]

§ 350.4 [Reserved]

§ 350.5 Application for service.

Any person who desires to receive service under the regulations in this part for meat or other product eligible therefor under such regulations may make application for service to the Administrator, upon an application form

which will be furnished by the Administrator upon request.

(Approved by the Office of Management and Budget under control number 0583–0036)

[23 FR 9982, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and at 35 FR 15554, Oct. 3, 1970, and amended at 47 FR 746, Jan. 7, 1982]

§ 350.6 Denial or withdrawal of service.

(a) If any person has applied for service for meat or other product not eligible therefor under the regulations in this part, or has failed to make proper application for service or to pay fees and charges due for service furnished or to be furnished to him under the regulations in this part, or if the service cannot be furnished to any person applying therefor because of lack of available inspectors or other administrative reasons, the service may be denied to such person by the Administrator until the condition justifying such denial is corrected.

(b) Service under the regulations in this part may also be denied to any person by the Secretary for such period as he may deem proper, if it is determined, after opportunity for hearing before a proper official in the Department, that such person has been responsible for any willful misrepresentation to the Department concerning any meat or other product for which service has been requested under the regulations, in this part, or that such person has been responsible for the use without authority, or the imitation, of any marks or certificates of Federal meat inspection on or with respect to any meat or other product, or has otherwise been responsible for any fraudulent or deceptive practice with respect to such service, or that such person has interfered with or obstructed any inspector in the performance of his duties under the regulations in this part, or attempted to do so. When the Administrator determines that the public interest so requires, he may deny or withdraw service provided for in this part, without a hearing, pending final determination of the matter. The applicant or recipient of service involved shall be notified of the Administrator's decision to deny or suspend service and the reasons therefor, in writing, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to deny or suspend the service shall be effective upon such oral or written notification, whichever is earlier, to the applicant or recipient of service. If such notification is oral, the Administrator shall confirm such decision and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the applicant or recipient of service, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)). In other cases prior to the institution of proceedings for denial of service under this paragraph, the facts or conduct which may warrant such action shall be called to the attention of the person involved, in writing, and he shall be given an opportunity to demonstrate or achieve compliance with all applicable requirements.

[23 FR 9982, Dec. 23, 1958; 25 FR 9642, Oct. 7, 1960. Redesignated at 30 FR 4195, Mar. 31, 1965, and 35 FR 15554, Oct. 3, 1970, and amended at 43 FR 11147, Mar. 17, 1978]

§ 350.7 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in accordance with this section, and, if required by the Administrator, the fees and charges shall be paid in advance.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the Treasurer of the United States and shall be remitted promptly to the Administrator upon furnishing to the applicant of a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rates specified in §§391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall cover the costs of the service and shall be charged for the time required to render such services. Where appropriate, this time will include, but will not be limited to, the

time required for travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover the cost of travel and other expenses incurred by the Service in connection with the furnishing of the service.

(e) Exporters that submit electronic export certificate applications will be charged a fee per application submitted.

(f) For each calendar year, FSIS will calculate the electronic export certificate application fee, using the following formula: Labor Costs (Technical Support Cost + Export Library Maintenance Cost) + Information Technology Costs (On-going operations Cost + Maintenance Cost + eAuthentication Cost), divided by the number of export applications.

(g) FSIS will publish notice of the electronic export certificate application fee annually in the FEDERAL REGISTER.

[23 FR 9982, Dec. 23, 1958, as amended at 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989; 81 FR 42234, June 29, 2016]

§ 350.8 Scope and applicability of rules of practice.

The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 350).

[43 FR 11147, Mar. 17, 1978]

PART 351—CERTIFICATION OF TECHNICAL ANIMAL FATS FOR EXPORT

DEFINITIONS

Sec.

SCOPE OF CERTIFICATION SERVICE

PROCEDURE FOR OBTAINING SERVICE: ADMINISTRATION OF PROGRAM

FEES

FACILITIES AND OPERATIONS

TRANSPORTATION AND EXPORTATION OF CERTIFIED TECHNICAL ANIMAL FAT

PROHIBITIONS

REMEDIES; PENALTIES

APPEALS

RECORDS AND REPORTS

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 40 FR 58627, Dec. 18, 1975, unless otherwise noted.

DEFINITIONS

§ 351.1 Meaning of words.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 351.2 Terms defined.

When used in this part, unless the context otherwise requires:

(a) *Department* means the United States Department of Agriculture.

(b) *Program* means the Meat and Poultry Inspection Program of the Food Safety and Inspection Service of the Department.

(c) *Administrator* means the Administrator of the Food Safety and Inspection Service of the Department, or any officer or employee of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(d) *Circuit supervisor* means an employee of the Program assigned to supervise and perform official work in a circuit. Such employee is assigned by and reports directly to the Administrator or person designated by him.

(e) *Inspector* means an employee of the Program or a cooperating State.

(f) *Circuit* means one or more inspected plants assigned to a circuit supervisor.

(g) *Recognized State* means any State not designated in § 331.2 of this chapter.

(h) *Cooperating State* means any State cooperating under § 351.7 in administration of the regulations in this part.

(i) *Inspection* means ante-mortem and post-mortem inspection by Program inspectors or inspectors of a Meat Inspection Service of a recognized State.

(j) *Animals* means cattle, sheep, swine, goats, horses, mules and other equines.

(k) *Technical animal fat* means animal fat eligible for exportation, or storage for exportation, in accordance with § 325.11 of this chapter.

(l) *Certified technical animal fat* means technical animal fat certified for export or storage for export under the regulations in this part.

(m) *Tallow* means technical animal fat with a minimum titre of 40 °C.

(n) *Certified plant* means any plant or storage facility preparing or storing certified technical animal fat for export, or for transfer to another certified plant or storage facility for ultimate export, and at which certification service is provided under the regulations in this part.

(o) *Inspected and Passed* means inspected and passed under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or the meat inspection laws of a recognized State.

SCOPE OF CERTIFICATION SERVICE

§ 351.3 Kind of service.

(a) Certification, in the form set forth in paragraph (b), is available under the regulations in this part for specific lots of technical animal fat for export, if the fat was rendered from materials derived from carcasses, or parts of carcasses, that had been inspected and passed and came from animals that did not die otherwise than by slaughter under inspection. The certification will be made by a Program employee when he determines, upon the basis of examinations made by him or other inspectors, as provided in § 351.14, and information obtained by him or them from the exporter or other sources, as provided in the regulations in this part, that the technical animal fat is eligible for certification under this section and therefore the statements to be certified are correct. The service will be available upon a voluntary fee basis in accordance with said regulations.

(b)(1) The form of Certificate for Export of Technical Animal Fats is as follows:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
MEAT AND POULTRY INSPECTION PROGRAM
WASHINGTON, D.C. 20250

CERTIFICATE FOR EXPORT OF TECHNICAL ANIMAL FATS

	1. KIND OF PRODUCT
	2. NET WEIGHT OF PRODUCT *(From Bill of Lading)*
3. NAME AND ADDRESS OF PLANT MAKING SHIPMENT CERTIFIED PLANT NO.	4. NAME AND ADDRESS OF TRANSPORTING COMPANY
5. NAME OF VESSEL	6. COUNTRY OF DESTINATION
7. VESSEL NUMBER	8. NAME OF CITY WHERE LOADED / 9. DATE LOADED

The Undersigned Certifies In Accordance With 9 CFR 351.3 That:

a. The product described above has been obtained by rendering raw materials, none of which were diseased, suspected of being diseased, or from dead animals.

b. The product covered by this certification has not been rendered under the continuous Federal inspection provided in the Federal Meat Inspection Act. For compliance with this certification, the plant equipment, plant conditions, and processing operations of the rendering plant(s) supplying the product certified by this certification are subject to Federal inspection on a periodic basis as authorized by the Agricultural Marketing Act and regulations thereunder *(9 CFR Part 351)*.

10. ISSUED AT *(Name of City)*	11. DATE ISSUED
12. SIGNATURE OF USDA INSPECTOR	

MP FORM 87
NOV. 1975

(2) Certified technical animal fat may be described on the certificate as ''technical animal fat''; or if it is tallow, it may be described on the certificate as ''Tallow'' and the description may include the statement ''titre not less than 40 °C.''

PROCEDURE FOR OBTAINING SERVICE: ADMINISTRATION OF PROGRAM

§ 351.4 Application for certification service.

Application for certification service under the regulations in this part may be made to the Administrator by the operator of any rendering plant or storage facility at which technical animal fat is prepared or stored for export. In case of a change of ownership or change of location, a new application shall be made. Applications shall be made on forms[1] available from the Administrator and provide all information called for thereon relating to the identity of the applicant and the plant, and the nature of the plant operations, and a certification of specified facts and an agreement to comply with specified requirements.

(Approved by the Office of Management and Budget under control number 0583–0036)

[40 FR 58627, Dec. 18, 1975, as amended at 47 FR 746, Jan. 7, 1982]

§ 351.5 Conditions of eligibility for certification service; review of applications.

(a) To be eligible for certification service under the regulations in this part, the operator of a rendering plant must demonstrate that:

(1) He operates a rendering plant which will receive materials derived from inspected and passed carcasses, or parts of carcasses, of animals that did not die otherwise than by slaughter under inspection, (i.e., not ''dead animals''); and such source materials will be rendered at the plant into technical animal fat eligible for export, or storage for export, in accordance with the regulations in this part;

(2) The source materials and the rendered technical animal fat described in paragraph (a)(1) will be identified and kept separated at all times from other products; and

[1] Copy filed as part of the original document.

(3) He will comply with the applicable regulations in this part.

(b) To be eligible for certification service under the regulations in this part, the operator of a storage facility must demonstrate that:

(1) He operates a storage facility that will receive for storage certified technical animal fat shipped directly from a certified rendering plant for storage for export and he will keep such shipments identified and separated from other products that are not certified, and he will receive such fat only if it is accompanied by MP Form 85, as required by § 351.17.

(2) He will comply with the applicable regulations in this part.

(c) Each applicant for certification service must file with the Administrator, with the application for service, a written description of the procedures to be used for receiving, identifying, processing, storing, and otherwise handling technical animal fat, and materials for use in the preparation thereof, at the plant or storage facility involved, and for shipping technical animal fat from the plant or facility and storing and exporting such technical animal fat, and a written description of the shipping, receiving, and inventory records maintained for technical animal fat.

(d) The Administrator will determine, on the basis of all information available to him, whether the arrangements at the plant or storage facility are such as will assure that certifications of technical animal fat will be correct, and, if so, will grant the application for certification service. An applicant will be given an opportunity to present his views prior to refusal of the service.

(Approved by the Office of Management and Budget under control number 0583–0036)

[40 FR 58627, Dec. 18, 1975, as amended at 41 FR 12637, Mar. 26, 1976; 47 FR 746, Jan. 7, 1982]

§ 351.6 Official number.

The Administrator will assign a certified technical animal fat plant number to each plant granted service. Such number shall be preceded by the letter ''C'' and be used to identify all certified technical animal fat prepared or stored by the plant.

§ 351.7 Administration of certification service program.

(a) The regulations in this part shall be administered by the circuit supervisor for the jurisdiction in which is located the certified plant or plants for which application for certification service is made, and such assistants as may be necessary will be assigned by the Administrator.

(b) The Administrator may enter into a cooperative agreement with any recognized State for the conduct by State employees of any surveys, examinations, and other activities involved in the administration of the regulations in this part. However, certifications under these regulations may be issued only by Program employees, as provided in § 351.3.

FEES

§ 351.8 Charges for surveys of plants.

Applicants for the certification service shall pay the Department for salary costs at the rates specified in §§ 391.2 and 391.3 respectively for base time, and for overtime, travel, and per diem allowances at rates currently allowed by the Federal Travel Regulations, and other expenses incidental to the initial survey of the rendering plants or storage facilities for which certification service is requested.

[54 FR 6389, Feb. 10, 1989]

§ 351.9 Charges for examinations.

(a) The fees to be charged and collected by the Administrator for examination shall be at the rates specified in §§ 391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays, as provided for in § 351.14; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs and which are required to determine the eligibility of any technical animal fat for certification under the regulations in this Part. Such fees shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith.

(b) Charges may also be made to cover the actual cost of travel and per

diem allowance at rates currently allowed by the General Services Administration, and other expenses incurred by the Department in connection with such examinations and laboratory service.

[40 FR 58627, Dec. 18, 1975, as amended at 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989]

FACILITIES AND OPERATIONS

§ 351.10 Facilities.

(a) Facilities for the preparation, identification, and storage of the technical animal fat to be certified shall be furnished and maintained by the certified plant in accordance with this section.

(b) The operator of the certified plant shall provide at the plant, rooms, compartments, and equipment needed to maintain the identity of certified technical animal fats and materials used in their preparation, and separation of such articles from other products. Such rooms, compartments, and equipment shall be conspicuously marked with the phrase ''Certified Technical Animal Fat'' whenever they contain these fats.

§ 351.11 Identification and separation of technical animal fats for certification and materials for use therein; removal of wrappers, etc.; cleaning of equipment.

(a) All technical animal fat to be offered for certification under this part and materials to be used in the preparation of such fat, and all certified technical animal fat, shall be identified and kept separate from other products from the time of receipt at a certified plant and throughout processing or handling at such plant. All wrappers and packaging shall be removed from the source materials to the fullest extent practicable before the materials are rendered at the plant.

(b) If a plant's operations are within the provisions of § 351.14(b)(3), all equipment shall be cleaned before it is used for receiving, preparation, or storage of certified technical animal fats or material to be used in preparation of such fats. Such cleaning shall be done in such manner as to prevent contamination of such certified fats or source material with materials that are unacceptable under § 351.3.

§ 351.12 Circuit supervisor to be informed when plant operates.

The operator of each certified plant shall inform the circuit supervisor, in advance, when the plant's work schedule will include preparing technical animal fats for certification and identify the approximate days and hours when operations will begin and end.

§ 351.13 Inspectors to have access to certified plants at all times.

For the purpose of administering the regulations in this part, inspectors shall have access at all times by day or night to every part of a certified plant.

§ 351.14 Processes to be supervised; extent of examinations.

(a) All processes used in the preparation of certified technical animal fats at any certified plant shall be subject to supervision by an inspector. Certified plants shall not prepare any technical animal fat for certification under the regulations in this part, except in accordance with such regulations.

(b) Supervision, ranging from full-time coverage of an entire process to one or more reviews per month, to determine a plant's compliance with the regulations in this part will be maintained. A circuit supervisor may increase the frequency of reviews whenever he deems necessary to assure the validity of certifications under the regulations in this part. Usual coverage of individual rendering plants will be as follows:

(1) Coverage shall be at least once a month if the plant consistently handles only raw materials acceptable under § 351.3 for the preparation of certified technical animal fat and the plant operator, in writing, certifies that he is maintaining this procedure.

(2) Coverage shall be at least once a week if the plant consistently handles some raw materials that are acceptable, and some that are unacceptable, under § 351.3, for the preparation of certified technical animal fat, uses separate equipment for processing, and uses separate rooms, compartments, and equipment for receiving and storing

the respective types of raw materials and technical animal fats, and the plant operator, in writing, certifies that he is maintaining this complete physical separation procedure.

(3) Coverage shall be fulltime during receiving of raw materials and their preparation into certified technical animal fat, if the plant handles some raw materials that are acceptable, and some that are unacceptable, under §351.3, for the preparation of certified technical animal fat, and uses the same rooms, compartments, and equipment, with only time separation between receiving, processing, and storing the respective types of raw materials and technical animal fats.

§ 351.15 Reports of violations.

Inspectors shall report to the circuit supervisor any apparent violations of the regulations in this part or the Federal Meat Inspection Act or regulations thereunder (subchapter A of this chapter) which occur at certified plants, or elsewhere, within their knowledge. The circuit supervisor shall report such actions to the Administrator through appropriate channels.

TRANSPORTATION AND EXPORTATION OF CERTIFIED TECHNICAL ANIMAL FAT

§ 351.16 Certificate required for shipments of technical animal fat.

No certified plant shall export any certified technical animal fat unless the shipment is accompanied by a certificate issued under §351.3.

§ 351.17 Identification required.

Certified technical animal fats being exported directly from a certified plant or transferred between certified plants for storage for export are subject to the requirements of §325.11 of this chapter. In addition, such shipments between certified plants shall be accompanied by MP Form 85 (Declaration to Accompany Technical Animal Fats Between Certified Technical Animal Fat Plants)[2] prepared by the operator of the certified plant from which shipment is made, certifying that the product has been obtained by rendering raw materials derived from federally or State inspected and passed carcasses, or parts of carcasses. Technical animal fat described on MP Form 85 as tallow must meet the definition of ''Tallow'' in §351.2.

[2] Copy filed as part of the original document.

PROHIBITIONS

§ 351.18 Official identifications; unauthorized use.

(a) The form of certification set forth in §351.3 and the term ''Certified Technical Animal Fat'' are official identifications for purposes of the Agricultural Marketing Act of 1946, as amended, and shall not be falsely made, issued, altered, forged, or counterfeited, or used for purpose of misrepresentation or deception.

(b) No container which bears or is to bear any designation as certified technical animal fat shall be filled in whole or in part, except with technical animal fats which have been certified and identified in compliance with this part.

REMEDIES; PENALTIES

§ 351.19 Refusal of certification for specific lots.

If an inspector has reason to believe that a lot of technical animal fat is ineligible for certification under §351.3, or any materials to be used in a lot of technical animal fat would make the technical animal fat ineligible for such certification, certification of the lot shall be withheld pending final determination by the circuit supervisor. The operator of the plant shall be afforded an opportunity to demonstrate the eligibility of the lot for certification before the final determination is made.

§ 351.20 Withdrawal of service from certified plants.

(a) After opportunity for hearing has been accorded the operator of a certified plant, the certification service, provided for in this part, may be withdrawn from such plant in accordance with the applicable rules of practice, if it is determined that:

(1) The operator, or his employee or agent:

(i) Has made any willful misrepresentation or engaged in any fraudulent or deceptive practice in connection with the service;

(ii) Has interfered with or obstructed any Program employee or other inspector in the performance of his duties, under the regulations in this part, by intimidation, threats, or other improper means; or

(iii) Has violated section 203(h) of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1622(h)), or any regulation in this part; or

(2) Facilities or procedures at the certified plant do not conform to the arrangements approved by the Administrator under §351.5.

(b) Pending final determination of the matter, the Administrator may summarily suspend the certification service at any certified plant when he has reason to believe that there is cause for withdrawal of the service under paragraph (a). The operator of the certified plant shall be notified of the Administrator's decision to suspend summarily the certification service at such plant and the reasons therefor, in writing, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to suspend summarily the certification service shall be effective upon such oral or written notification, whichever is earlier, to the operator of the certified plant. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator of the certified plant, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(c) The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 351).

[40 FR 58627, Dec. 18, 1975, as amended at 43 FR 11148, Mar. 17, 1978]

APPEALS

§351.21 Appeals.

Any decision by an employee of the Program may be appealed by any adversely affected person to the immediate supervisor of such employee. Decisions of other inspectors may be appealed to the circuit supervisor.

RECORDS AND REPORTS

§351.22 Certified plants to maintain records and make reports; access to records.

(a) Each day a certified plant prepares, receives, or ships certified technical animal fat or receives material for use in such product, the operator of the plant shall prepare records identifying the kinds and quantities of such materials and technical animal fats received, the number of pounds of certified technical animal fat prepared or shipped, and an up-to-date inventory of certified technical animal fats in storage. The operator of each certified plant shall include in the records required by this section all MP Forms 85 which he receives with shipments of certified technical animal fat from any other certified plant. These records shall be maintained by the operator of each certified plant and made available to an inspector, upon request, for examination and copying, for a period of 1 year after the date of the transaction involved.

(b) The operator of each certified plant shall provide such relevant information as any inspector may request to enable him to determine whether any technical animal fats are eligible for certification and whether the plant is eligible for certification service under the regulations in this part.

(Approved by the Office of Management and Budget under control number 0583–0036)

[40 FR 58627, Dec. 18, 1975, as amended at 47 FR 746, Jan. 7, 1982]

PART 352—EXOTIC ANIMALS AND HORSES; VOLUNTARY INSPECTION

Subpart A—Exotic Animals

Sec.

Subpart B—Horses

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 50 FR 41847, Oct. 16, 1985, unless otherwise noted.

Subpart A—Exotic Animals

§ 352.1 Definitions.

The definitions in § 301.2, not otherwise defined in this part, are incorporated into this part. In addition to those definitions, the following definitions will be applicable to the regulations in this part.

(a) *Act* means the applicable provisions of the Agricultural Marketing Act of 1946, as amended (60 Stat. 1087, as amended; 7 U.S.C. 1621 *et seq.*).

(b) *Acceptable* means suitable for the purpose intended and acceptable to the Food Safety and Inspection Service.

(c) *Antelope* means any animal belonging to the antelope family.

(d) *Applicant* means any interested party who requests any inspection service.

(e) *Bison* means any American bison or catalo or cattalo.

(f) *Buffalo* means any animal belonging to the buffalo family.

(g) *Catalo* or *Cattalo* means any hybrid animal with American bison appearance resulting from direct crossbreeding of American bison and cattle.

(h) *Condition* means any condition, including, but not limited to, the state of preservation, cleanliness, or soundness of any product or the processing, handling, or packaging which may affect such product.

(i) *Condition and wholesomeness* means the condition of any product, its healthfulness and fitness for human food.

(j) *Deer* means any member of the deer family.

(k) *Exotic animal* means any reindeer, elk, deer, antelope, water buffalo or bison.

(l) *Elk* means any American elk.

(m) *Exotic animal inspection service* means the personnel who are engaged in the administration, application, and direction of exotic animal inspection programs and services pursuant to the regulations in this part.

(n) *Exotic animal producer* means any interested party that engages in the raising and/or marketing of an exotic animal for commercial purposes.

(o) *Field ante-mortem inspection* means the ante-mortem inspection of an exotic animal away from the official exotic animal establishment's premises.

(p) *Field designated area* means any designated area on the applicant's premises, approved by the Regional Director, where field ante-mortem inspection is to be performed.

(q) *Identify* means to apply official identification to products or containers.

(r) *Inspection* means any inspection by an inspector to determine, in accordance with regulations in this part, (1) the condition and wholesomeness of an exotic animal, or (2) the condition and wholesomeness of edible product of an exotic animal at any state of the preparation or packaging in the official plant where inspected and certified, or (3) the condition and wholesomeness of any previously inspected and certified product of an exotic animal if such product has not lost its identity as an inspected and certified product.

(s) *Interested party* means any person financially interested in a transaction involving any inspection.

(t) *Official exotic animal establishment* means any slaughtering, cutting, boning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this part.

(u) *Official device* means a stamping appliance, branding device, stencil printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or packaging material.

(v) *Official identification* means any symbol, stamp, label or seal indicating that the product has been officially inspected and/or indicating the condition of the product approved and authorized by the Administrator to be affixed to any product, or affixed to or printed on the packaging material of any product.

(w) *Program* means the Voluntary Exotic Animal Inspection Program of the Food Safety and Inspection Service.

(x) *Reindeer* means any reindeer commonly referred to as caribou.

(y) *Transport vehicle* means any vehicle used to transport an exotic animal.

(z) *Veterinarian* means an authorized veterinarian of the Program employed by the Department or any cooperating State who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

(aa) *Water buffalo* means any Asiatic water buffalo, commonly referred to as carabao; and the water buffalo of India, commonly referred to as the Indian buffalo.

[54 FR 1330, Jan. 13, 1989]

§ 352.2 Type of service available.

Upon application, in accordance with §§ 352.3, 352.4, and 352.5, the following type of service may be furnished under the regulations in this part:

(a) Voluntary Inspection Service. An inspection and certification service for wholesomeness relating to the slaughter and processing of exotic animals and the processing of exotic animal products. All provisions of this part shall apply to the slaughter of exotic animals, and the preparation, labeling, and certification of the exotic animal meat and exotic animal products processed under this exotic animal inspection service.

(b) Only exotic animals which have had ante-mortem inspection as described under this part and which are processed in official exotic animal establishments in accordance with this part may be marked inspected and passed.

(c) Exotic animals, exotic animal meat and meat food products shall be handled in an official exotic animal establishment to ensure separation and identity of the exotic animal or exotic animal meat and meat food products until they are shipped from the official exotic animal establishment to prevent commingling with other species.

[54 FR 1330, Jan. 13, 1989]

§ 352.3 Application by official exotic animal establishment for inspection services.

(a) Any person desiring to process an exotic animal, exotic animal carcasses, exotic animal meat and meat food products in an establishment under exotic animal inspection service must receive approval of such establishment and facilities as an official exotic animal establishment prior to the rendition of such service. An application for inspection service to be rendered in an official exotic animal establishment shall be approved in accordance with the provisions contained in §§ 304.1 and 304.2 of subchapter A of this chapter.

(b) Initial survey. When an application has been filed for exotic animal inspection service, the Regional Director or designee, shall examine the establishment, premises, and facilities.

[54 FR 1331, Jan. 13, 1989]

§ 352.4 Application for ante-mortem inspection service in the field.

Any exotic animal producer desiring field ante-mortem exotic animal inspection service must receive approval of the field ante-mortem designated area from the Regional Director or designee prior to the rendition of such service. An application seeking approval of the designated area for ante-mortem inspection shall be obtained from the Regional Director, and completed and submitted to the Regional Director.

(a) An initial application for field ante-mortem exotic animal inspection service shall be made by an official exotic animal establishment to the Regional Director. Subsequent requests

shall be made by the official exotic animal establishment on behalf of an exotic animal producer to the Regional Director in one of the following manners: (1) telephone, (2) telegraph, (3) mail, or (4) in person as determined by the Regional Director.

(b) Upon receipt of the completed application, the Regional Director or designee shall examine the field antemortem designated area and facilities for approval of the designated area.

(c) All fees involved for the approval of the designated area, including but not limited to any travel, per diem costs, and time required to perform such approval services, shall be paid directly by the applicant to the Regional Director.

[54 FR 1331, Jan. 13, 1989]

§ 352.5 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in accordance with this section.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the ''Treasurer of the United States'' and shall be remitted promptly to the Regional Director upon furnishing to the applicant a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rates specified in §§ 391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall cover the costs of the service and shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover other expenses incurred by the Service in connection with the furnishing of the service.

(e) Fees and charges for any inspection pursuant to a cooperative agreement with any State shall be paid in accordance with the terms of such cooperative agreement.

[50 FR 41847, Oct. 16, 1988, as amended at 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 352.6 Denial or withdrawal of inspection service.

(a) *For miscellaneous reasons.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person, without a hearing by the appropriate Regional Director: (1) for administrative reasons such as the nonavailability of personnel to perform the service; (2) for the failure of payment for service; (3) in case the application or request relates to exotic animals or exotic animal products which are not eligible for service under this part; (4) for failure to maintain the designated area or the plant in a state of repair approved by the Service; (5) for the use of operating procedures which are not in accordance with the regulations of this part; (6) for alterations of buildings, facilities, or equipment which cannot be approved under the regulations in this part. Notice of such rejection, denial, or withdrawal, and the reasons therefore, shall promptly be given to the person involved. The applicant or recipient shall be notified of such decision to reject an application or request for service or to deny or withdraw the benefits of the service, and the reasons therefor, in writing in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. Such decision shall be effective upon such oral or written notification, whichever is earlier, to the applicant or recipient. If such notification is oral, the person making such decision shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the applicant or recipient in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)).

(b) *For disciplinary reasons—Basis for denial or withdrawal.* An application or request for service may be denied, or the benefits of the service may be withdrawn from, any person or entity who, or whose officer, employee or agent in

the scope of his employment or agency: (1) Has willfully made any misrepresentation or has committed any other fraudulent or deceptive practice in connection with any application or request for service under this part; (2) has given or attempted to give, as a loan or for any other purpose, any money, favor or other thing of value, to any employee or agent of the Department or a cooperating State authorized to perform any function under this part; (3) has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee or agent of the Department or cooperating State in the performance of his or her duties under this part by intimidation, threats, assaults, abuse, or any other improper means; (4) has knowingly represented that any exotic animal carcass, or exotic animal product, has been officially inspected and passed by an authorized inspector under this part, when it had not, in fact, been so inspected; (5) has been convicted of more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged good, or fraud in connection with transactions in food, or any felony; *Provided*, an application or a request for service made in the name of a person or entity otherwise eligible for service under the regulations may be denied, or the benefits of the service may be withdrawn, from such a person or entity in case the service is or would be performed at a location operated by a person or entity, from whom the benefits of the service are currently being denied or have been withdrawn under this part; or by a person or entity having an officer, director, partner, manager or substantial investor from whom the benefits of service under this part are currently being denied or have been withdrawn under this part, and who has any authority with respect to the location where service is or would be performed; or in case the service is or would be performed with respect to any exotic animal or exotic animal product in which any person or entity, from whom the benefits of service are currently being denied or have been withdrawn under this part, has contract or other financial interest.

(c) *Procedure.* (1) An application or request for service may be denied or benefits of the service may be withdrawn by the Secretary, as provided by paragraph (b) of this section, after notice and opportunity for hearing before a designated official of the Department. The Administrator may suspend service under this paragraph without hearing, pending final determination of the matter, when he determines that the public health, interest or safety so requires. The applicant or recipient shall be notified of the Administrator's decision to suspend service, and the reasons therefor, in writing or orally. The Administrator's decision to suspend service under this part shall be effective upon such an oral or written notification, whichever is earlier, to the applicant or recipient. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the applicant or recipient in the manner prescribed in 1.147(b) of Departmental rules of practice (7 CFR 1.147(b)).

(2) The written notification specified in paragraph (c) of this section, which shall constitute the complaint in the proceeding, shall briefly set forth the reason for the denial or withdrawal of service, including allegations of fact which constitute a basis for the action. After the complaint is served upon the respondent, as provided in §1.147(b) of Departmental rules of practice (7 CFR 1.147(b)), the proceeding shall thereafter be conducted in accordance with rules of practice which shall be adopted for the proceeding.

[50 FR 41847, Oct. 16, 1985, as amended at 54 FR 1331, Jan. 13, 1989]

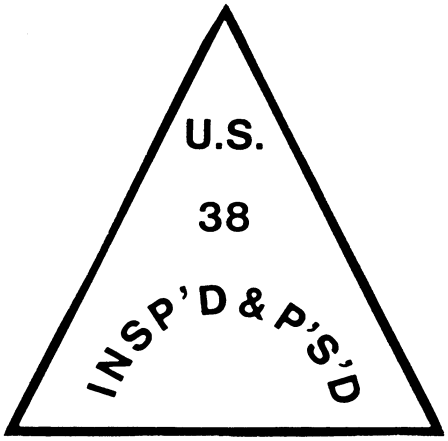
§ 352.7 Marking inspected products.

Wording and form of inspection mark. Except as otherwise authorized by the Administrator, the inspection mark applied to inspected and passed exotic animal carcasses, meat or meat food products under this part shall include wording as follows: ''Inspected and Passed by U.S. Department of Agriculture.'' This wording shall be contained within a triangle in the form and arrangement shown in this section.

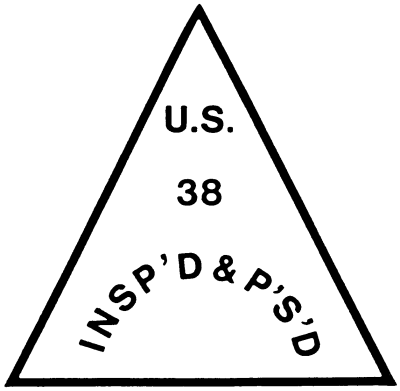
The establishment number of the official establishment shall be included in the triangle unless it appears elsewhere on the packaging material. Ordering and manufacture of the triangle brand shall be in accordance with the provisions in 9 CFR 317.3(c) of the Federal meat inspection regulations. The Administrator may approve the use of abbreviations of such inspection mark, and such approved abbreviations shall have the same force and effect as the inspection mark. The inspection mark or approved abbreviation shall be applied, under the supervision of the inspector, to the inspected and passed edible product, packaging material, immediate container or shipping container. When the inspection mark or approved abbreviation is used on packaging material, immediate container or shipping container, it shall be printed on such material or container or on a label to be affixed to the packaging material or container. The name and address of the packer or distributor of such product shall be printed on the packaging material or label. The inspection marks may be stenciled on the container, and when the inspection mark is so stenciled, the name and address of the packer or distributor may be applied by the use of a stencil or rubber stamp. The name and address of the packer or distributor, if prominently shown elsewhere on the packaging material or container, may be omitted from insert labels which bear an official identification if the applicable establishment number is shown.

(a) The inspection mark to be applied to inspected and passed carcasses and parts of carcasses of an exotic animal, and products as therefrom approved by the Administrator, shall be in the form and arrangement as indicated in the example below.[1] The establishment number of the official establishment shall be set forth if it does not appear on the packaging material or container.

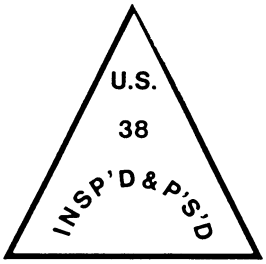
(1) For application to exotic animal carcasses, primal parts and cuts therefrom, exotic animal livers, exotic animal tongues, and exotic animal hearts.



(2) For application to exotic animal calf carcasses.

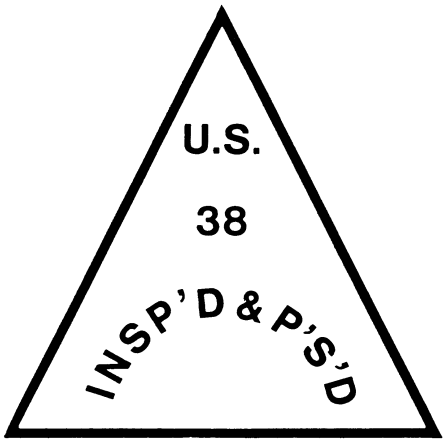


(3) For application to exotic animal tails.



(4) For application to burlap, muslin, cheesecloth, heavy paper, or other acceptable material that encloses carcasses or parts of carcasses.

[1] The number ''38'' is given as an example only. The establishment number of the official exotic animal establishment where the product is prepared shall be used in lieu thereof.



(b) The official inspection mark to be shown on all labels.[1] (1) For inspected and passed products of an exotic animal shall be in the following form, except that it need not be of the size illustrated, provided that it is a sufficient size and of such color as to be conspicuously displayed and readily legible and the same proportions of letter size and boldness are maintained as illustrated:

(2) This official mark shall be applied by mechanical means and shall not be applied by a hand stamp.

(3) The official inspection legend described in paragraph (b)(1) of this section shall also be used on shipping containers, bond labels, artificial casings, and other articles with the approval of the Administrator.

(c) Any brand, stamp, label or other device approved by the Administrator and bearing any official mark prescribed in paragraph (a) or (b) of this section shall be an official device for purposes of the Act.

[50 FR 41847, Oct. 16, 1985, as amended at 54 FR 1331, Jan. 13, 1989]

§ 352.8 Time of inspection in the field and in an official exotic animal establishment.

The official exotic animal establishment on behalf of the applicant shall notify the Regional Director or designee, in advance, of the hours when such inspection is desired. Inspection personnel shall have access at all times to every part of any field ante-mortem inspection area and/or official exotic animal establishment to which they are assigned.

[54 FR 1332, Jan. 13, 1989]

§ 352.9 Report of inspection work.

Reports of the work of inspection carried on within the field ante-mortem inspection area of an exotic animal producer's premises and/or official exotic animal establishment shall be forwarded to the Administrator by the ante-mortem inspector. The applicant for such inspection shall furnish to the Administrator such information as may be required on forms provided by the Administrator.

[54 FR 1333, Jan. 13, 1989]

§ 352.10 Ante-mortem inspection.

An ante-mortem inspection of an exotic animal shall, where and to the extent considered necessary by the Administrator and under such instructions as he may issue from time to time, be made on the day of slaughter of an exotic animal, in one of the following listed ways or as determined by the Administrator. Humane handling of an exotic animal during ante-mortem inspection shall be in accordance with the provisions contained in 9 CFR 313.2. Immediately after the animal is stunned or killed, it shall be shackled, hoisted, stuck and bled.

[1] The number ''38'' is given as an example only. The establishment number of the official exotic animal establishment where the product is prepared shall be used in lieu thereof.

(a) To be performed on an exotic animal in the field in a designated area of an exotic animal producer's premises.

(1) Reindeer, elk, deer, antelope, bison and water buffalo are eligible for field ante-mortem inspection. The field ante-mortem designated area must be approved by the Regional Director or designee prior to rendition of the service.

(2) Any person who desires to receive field ante-mortem inspection must provide:

(i) Notification from an official exotic animal establishment to the Regional Director or designee.

(ii) A field ante-mortem designated area.

(iii) A stunning/slaughtering area which is in a condition that minimizes the possibility of soiling the animal when stunned/slaughtered and bled as determined by the inspector.

(iv) A transport vehicle that is as sanitary as practicable as determined by the inspector.

(3) The ante-mortem inspector shall determine the acceptableness and safety of performing field ante-mortem inspection. If, in the opinion of the ante-mortem inspector, an unsafe circumstance exists at the time of field ante-mortem inspection, the service shall be denied.

(4) An exotic animal that, in the ante-mortem inspector's opinion, does not pass ante-mortem inspection must be withheld from slaughter.

(5) Stunning to render the animal unconscious shall be in accordance with 9 CFR 313.15 or 313.16.

(6) All stunned/slaughtered and bled exotic animals shall be tagged with a ''U.S. Suspect'' tag in an ear by the ante-mortem inspector or designee prior to loading on the transport vehicle.

(7) The transport of intact exotic animal carcasses to an official exotic animal establishment for post-mortem inspection shall be as expedient as possible, and must be within the same day as field slaughter.

(8) Ante-mortem cards (Form MP 402–2) shall be filled out by the ante-mortem inspector. One copy is to be retained by the ante-mortem inspector. The other copy shall accompany the transport vehicle to the official exotic animal establishment and shall be delivered to the post-mortem veterinarian.

(9) The ante-mortem inspector shall supervise all phases of field ante-mortem inspection.

(b) To be performed on exotic animals that are inside of the transport vehicle at an official exotic animal establishment.

(1) Reindeer, elk, deer, antelope, bison, and water buffalo are eligible for transport vehicle inspection.

(2) The ante-mortem inspector shall remain outside the transport vehicle while performing ante-mortem inspection.

(3) The person requesting transport vehicle inspection must provide a transport vehicle that is as sanitary as practicable and that would safely and thoroughly permit the inspection of an exotic animal from outside of the transport vehicle as determined by the inspector.

(4) The ante-mortem inspector shall determine the adequacy and safety of performing ante-mortem inspection. If, in the ante-mortem inspector's opinion, the transport vehicle is not adequate or safe to perform ante-mortem inspection, the service shall be denied.

(c) To be performed in pens at official exotic animal establishments. The inspection shall be conducted in accordance with the provisions contained in 9 CFR part 309.

[54 FR 1333, Jan. 13, 1989]

§ 352.11 Post-mortem inspection.

(a) Post-mortem inspection of reindeer, elk, deer, antelope, bison and water buffalo shall be conducted in accordance with the provisions contained in 9 CFR part 310 or as determined by the Administrator.

(b) The post-mortem examination of field ante-mortem-inspected exotic animals must occur in the shortest length of time practicable and on the day that field ante-mortem inspection is performed to minimize the changes in the carcass which can affect the post-mortem examination, disposition and wholesomeness of the carcass and its parts.

(c) The post-mortem veterinarian shall inspect and make the disposition

of all incoming ''U.S. Suspect'' tagged exotic animals.

[54 FR 1333, Jan. 13, 1989]

§ 352.12 Disposal of diseased or otherwise adulterated carcasses and parts.

This shall be conducted in accordance with the provisions contained in 9 CFR part 311.

§ 352.13 Handling and disposal of condemned or other inedible exotic animal products at official exotic animal establishments.

This shall be conducted in accordance with the provisions contained in 9 CFR part 314.

§ 352.14 Entry into official establishments; reinspection and preparation of products.

This shall be conducted in accordance with the provisions contained in 9 CFR 318.1, 318.2, and 318.3.

§ 352.15 Records, registration, and reports.

This shall be conducted or maintained in accordance with the provisions contained in 9 CFR 320.1 through 320.7.

§ 352.16 Exports.

This shall be conducted in accordance with the provisions contained in 9 CFR 322.1 through 322.5.

§ 352.17 Transportation.

This shall be conducted in accordance with the provisions contained in §§ 325.1 through 325.21.

§ 352.18 Cooperation of States in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of States in carrying out Federal functions.

Subpart B—Horses

§ 352.19 Ante-mortem inspection and applicable requirements.

Notwithstanding part 309 of this subchapter, an official establishment that wishes to slaughter horses can apply for voluntary ante-mortem inspection according to § 352.3. Such establishments shall pay the applicable base time, overtime, and holiday rates for ante-mortem inspection in accordance with § 352.5. Such ante-mortem inspection shall be made in pens on the premises of the establishment at which the horses are offered for slaughter in accordance with § 309.1(b), and such establishments also shall comply with all applicable provisions of §§ 352.8 and 352.9. If the establishment complies with all these requirements for ante-mortem inspection, FSIS will conduct ante-mortem inspection at that establishment in accordance with § 352.10, and all other provisions in part 309 of this subchapter that pertain to horses will apply. FSIS may deny or withdraw ante-mortem inspection services at official establishments that slaughter horses for any applicable reason under § 352.6. Official marks and devices to identify inspected and passed horse carcasses and parts of carcasses, or horse meat food products shall be those in § 312.3 of this subchapter.

[71 FR 6341, Feb. 8, 2006]

PART 354—VOLUNTARY INSPECTION OF RABBITS AND EDIBLE PRODUCTS THEREOF

GENERAL

Sec.

ADMINISTRATION

BASIS OF SERVICE

PERFORMANCE OF SERVICES

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 41 FR 23702, June 11, 1976, unless otherwise noted.

GENERAL

§ 354.1 Definitions.

Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Act* means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087; 7 U.S.C. 1621 *et seq.*) or any other act of Congress conferring like authority.

(b) *Acceptable* means suitable for the purpose intended and acceptable to the Service.

(c) *Administrator* means the Administrator of the Food Safety and Inspection Service of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

(d) *Applicant* means any interested party who requests any inspection service.

(e) *Area supervisor* means any employee of the Department in charge of rabbit inspection service in a designated geographical area.

(f) *Carcass* means any rabbit carcass.

(g) *Circuit supervisor* or *technical supervisor* means the officer in charge of the rabbit inspection service in a circuit consisting of a group of stations within an area.

(h) *Class* means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind.

(i) *Condition* means any condition, including, but not being limited to, the state of preservation, cleanliness, or soundness, of any product or the processing, handling, or packaging which may affect such product.

(j) *Condition and wholesomeness* means the condition of any product, its healthfulness and fitness for human food.

(k) *Department* means the United States Department of Agriculture.

(l) *Edible product* means any product derived from ready-to-cook domestic rabbits.

(m) *Giblets* means the liver from which the bile sac has been removed and the heart from which the pericardial sac has been removed.

(n) *Holiday* or *legal holiday* shall mean the legal public holidays specified by the Congress in paragraph (a) of section 6103, Title 5, of the United States Code.

(o) *Identify* means to apply official identification to products or to containers thereof.

(p) *Inspected and certified* or *certified* means, with respect to any product, that it has undergone an inspection and was found, at the time of such inspection, to be sound, wholesome, and fit for human food.

(q) *Inspection, inspection service,* or *inspection of products for condition and wholesomeness* means any inspection by an inspector to determine, in accordance with the regulations in this part, (1) the condition and wholesomeness of rabbits, or (2) the condition and wholesomeness of any edible product at any state of the preparation or packaging thereof in the official plant where inspected and certified, or (3) the condition and wholesomeness of any previously inspected and certified product if such product has not lost its identity as an inspected and certified product.

(r) *Inspection certificate* means a statement, either written or printed, issued by an inspector, pursuant to the regulations in this part, relative to the

condition and wholesomeness of products.

(s) *Inspector* means any person who is licensed by the Secretary to investigate and certify, in accordance with the regulations in this part, the condition and wholesomeness of products. An inspector is an employee of the Department or of a State; he may be a graduate veterinarian or a layman.

(t) *Interested party* means any person financially interested in a transaction involving any inspection.

(u) *National supervisor* means (1) the officer in charge of the rabbit inspection service of the Food Safety and Inspection Service, and (2) other officers or employees of the Department designated by the officer in charge of the rabbit inspection service of the Food Safety and Inspection Service.

(v) *Official plant* means one or more buildings or parts thereof, comprising a single plant in which the facilities and methods of operation therein have been approved by the Administrator as suitable and adequate for operation under inspection service and in which inspection is carried on in accordance with the regulations in this part.

(w) *Person* means any individual, partnership, association, business trust, corporation, or any organized group of persons, whether incorporated or not.

(x) *Potable water* means water that has been approved by the State health authority as safe for drinking and suitable for food processing.

(y) *Product* means ready-to-cook cooked rabbits, or edible products derived therefrom.

(z) *Rabbit* means any domesticated rabbit, whether live or dead.

(aa) *Rabbit inspection service* means the personnel who are engaged in the administration, application, and direction of rabbit inspection programs and services pursuant to the regulations in this part.

(bb) *Ready-to-cook domestic rabbit* means any rabbit which has been slaughtered for human food, from which the head, blood, skin, feet, and inedible viscera have been removed, that is ready to cook without need of further processing. Ready-to-cook rabbit also means any cut-up or disjointed portion of rabbit or any edible part thereof, as described in this paragraph.

(cc) *Regulations* means the provisions of this entire part as may be in effect at the time inspection is performed.

(dd) *Secretary* means the Secretary of the Department, or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated, the authority to act in his stead.

(ee) *Service* means the Food Safety and Inspection Service of the Department.

(ff) *Station supervisor* means any authorized individual who is designated to supervise rabbit inspection service in a large official plant or in a group of several small plants.

§ 354.2 Designation of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended by Pub. L. 272, 84th Congress, provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications, and devices for making such marks or identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed in this section shall have the respective meanings specified:

(a) *Official certificate* means any form of certification, either written or printed, used under this part to certify with respect to the inspection or class or condition of products.

(b) *Official memorandum* means any initial record of findings made by an authorized person in the process of inspecting or sampling, pursuant to this part, any processing or plant operation report made by an authorized person in connection with inspecting or sampling under this part, and any report made by an authorized person of services performed pursuant to this part.

(c) *Official mark* means the inspection mark, and any other mark, or any variations in such marks, approved by the

Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product, stating that the product was inspected, or indicating the condition of the product, or for the purpose of maintaining the identity of products inspected under this part, including, but not limited to, that set forth in § 354.65.

(d) *Official identification* means any symbol, stamp, label, or seal indicating that the product has been officially inspected and/or indicating the class or condition of the product approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product.

(e) *Official device* means a stamping appliance, branding device, stencil, printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or the packaging material thereof.

ADMINISTRATION

§ 354.3 Administration.

The Administrator shall perform, for and under the supervision of the Secretary, such duties as are prescribed in the regulations in this part and as the Secretary may require in the administration of the regulations in this part. The Administrator is authorized to waive for limited periods any particular provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements and, at the same time, to assure full compliance with the spirit and intent of the regulations. The Food Safety and Inspection Service and its officers and employees shall not be liable in damages through acts of commission or omission in the administration of this part.

BASIS OF SERVICE

§ 354.10 Inspection service.

Any inspection service in accordance with the regulations in this part shall be for condition and wholesomeness.

§ 354.12 Eligibility.

(a) Only rabbits which are processed in official plants in accordance with the regulations in this part may be inspected.

(b) All rabbits that are eviscerated in an official plant where inspection service is maintained shall be inspected for condition and wholesomeness and no dressed rabbits or uninspected products shall be brought into such official plant.

§ 354.13 Supervision.

All inspection service shall be subject to supervision at all times by the station supervisor, circuit supervisor, area supervisor, and national supervisor. Such service shall be rendered where the facilities and conditions are satisfactory for the conduct of the service and the requisite inspectors are available.

§ 354.14 Authority to waive provisions of § 354.12.

The Administrator is authorized to waive the provisions of § 354.12 which pertain to the entry of uninspected edible products into official plants in specific instances where rabbits are to be brought into compliance with a law under the provisions of a court order. Such rabbits shall be handled in an official plant in accordance with such procedures as the Administrator may prescribe to insure proper segregation and identity of the rabbits or rabbit products until they are shipped from the official plant.

PERFORMANCE OF SERVICES

§ 354.20 Licensed or authorized inspectors.

(a) Any person who is a Federal or State employee or the employee of a local jurisdiction possessing proper qualifications as determined by an examination for competency, and who is to perform inspection service under this part may be licensed or otherwise authorized by the Secretary as an inspector.

(b) All licenses issued by the Secretary shall be countersigned by the officer in charge of the rabbit inspection service of the Animal and Plant Health

Inspection Service or any other designated officer of such Service.

§ 354.21 Suspension of license; revocation.

Pending final action by the Secretary, any person authorized to countersign a license to perform inspection service may, whenever he deems such action necessary to assure that any inspection service is properly performed, suspend any license to perform inspection service issued pursuant to this part, by giving notice of such suspension to the respective licensee, accompanied by a statement of the reasons therefor. Within 7 days after the receipt of the aforesaid notice and statement of reasons, the licensee may file an appeal in writing, with the Secretary, supported by any argument or evidence that he may wish to offer as to why his license should not be further suspended or revoked. After the expiration of the aforesaid 7–day period and consideration of such argument and evidence, the Secretary will take such action as he deems appropriate with respect to such suspension or revocation. When no appeal is filed within the prescribed 7 days, the license to perform inspection service is revoked.

§ 354.22 Surrender of license.

Each license which is suspended, or revoked, or has expired shall promptly be surrendered by the licensee to his immediate superior. Upon termination of the services of a licensed inspector, the licensee shall promptly surrender his license to his immediate superior.

§ 354.23 Identification.

Each inspector shall have in his possession at all times, and present upon request while on duty, the means of identification furnished by the Department to such person.

§ 354.24 Financial interest of inspectors.

No inspector shall render service on any product in which he is financially interested.

§ 354.25 Political activity.

All inspectors are forbidden, during the period of their respective appointments or licenses, to take an active part in political management or in political campaigns. Political activity in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, or any measure to be voted upon, is prohibited. This applies to all appointees, including, but not being limited to, temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of §§ 354.20 to 354.25 will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

§ 354.26 Schedule of operation of official plants.

Inspection operating schedules for services performed pursuant to § 354.107 shall be requested in writing and be approved by the Administrator. Normal operating schedules for a full week consist of a continuous 8-hour period per day (excluding not to exceed 1 hour for lunch), 5 consecutive days per week, within the period of Monday through Saturday, for each shift required. Less than 8-hour schedules may be requested and will be approved if an inspector is available. Sundays may not be approved in any tour of duty. Clock hours of daily operations need not be specified in the request, although as a condition of continued approval, the hours of operation shall be reasonably uniform from day to day. Inspectors are to be notified by management 1 day in advance of any change in the hours inspection service is requested.

APPLICATION FOR INSPECTION SERVICE

§ 354.30 Who may obtain inspection service.

An application for inspection service may be made by any interested person, including, but not being limited to, the United States, any State, county, municipality, or common carrier, and any authorized agent of the foregoing.

§ 354.31 How application for service may be made; conditions of resident service.

(a) On a fee basis. An application for any inspection service on a fee basis may be made in any office of inspection or with any inspector at or nearest the place where the service is desired.

Such application may be made orally (in person or by telephone), in writing, or by telegraph. If the application for inspection service is made orally, the office of inspection or the inspector with whom the application is made, or the Administrator, may require that the application be confirmed in writing.

(b) On a resident inspection basis. An application for resident inspection service must be made in writing on forms approved by the Administrator and filed with the Administrator. Such forms may be obtained at the national, area, or State inspection office. In making application, the applicant agrees to comply with the terms and conditions of the regulations (including, but not being limited to, such instructions governing inspection of products as may be issued from time to time by the Administrator). No member of or delegate to Congress or Resident Commissioner shall be admitted to any benefit that may arise from such service unless derived through service rendered a corporation for its general benefit.

§ 354.32 Filing of application.

An application for inspection service shall be regarded as filed only when made pursuant to the regulations in this part.

§ 354.33 Authority of applicant.

Proof of the authority of any person applying for inspection service may be required at the discretion of the Administrator.

§ 354.34 Application for inspection service in official plants; approval.

Any person desiring to process and pack products in a plant under inspection service must receive approval of such plant and facilities as an official plant prior to the rendition of such service. An application for inspection service to be rendered in an official plant shall be approved according to the following procedure:

(a) Initial survey. When application has been filed for inspection service as aforesaid, the area supervisor, or his assistant, shall examine the plant, premises, and facilities and shall specify any additional facilities required for the service. Appeals with respect to any such specification may be made to the national supervisor.

(b) Drawings and specifications to be furnished in advance of construction or alterations.

(1) Four copies of drawings or blueprints showing the features specified herein shall be submitted to the Administrator. The drawings or blueprints shall be legible, made with sharp, clear lines, and properly drawn to scale, and shall consist of floor plans and a plot plan.

(2) The plot plan shall show such features as the limits of the plant's premises, locations in outline of buildings on the premises, one point of the compass, and roadways and railroads serving the plant.

(3) The floor plan shall show all space to be included in the official plant. If rooms or compartments shown on the drawings or blueprints are not to be included as part of the official plant, this shall be clearly indicated thereon.

(4) The sheets of paper on which drawings or blueprints are made shall not exceed a size 34″ × 44″. The drawings other than of the plot plan shall be made to a scale of ⅛″ per foot, except that additional plans for some areas showing detail may be drawn to a scale of ¼″ per foot. The plot plan may be drawn to a scale of not less than 1/32″ per foot. The drawings shall indicate the scale used and shall also indicate the floor shown (e.g., basement, first, or second).

(c) Features required to be shown on floor plan. The following features shall be shown on the floor plan:

(1) The principal pieces of equipment drawn to scale in the proper locations.

(2) The name of the firm and the address of the plant by street and street number, or by other means properly identifying the location of the plant.

(3) One point of the compass.

(4) The doors and openings for passageways, designating those which are self-closing or permanently closed.

(5) All floor drain openings and gutter drains.

(6) Lavatories in toilet and processing rooms (lavatories which are other than hand-operated shall be so designated on the drawings or blueprints).

(7) All steam and hot and cold water outlets for cleanup purposes.

(8) Ice-making and storage facilities.

(9) The point at which live rabbits are hung on the conveyor line, the point at which the ready-to-cook rabbits are removed, and any intermediate transfer points.

(10) The routes of the edible and inedible products.

(11) The location of fresh air inlets, exhaust fans, and hoods.

(d) Specifications. Specifications covering the following items shall accompany the drawings:

(1) Height of ceilings.

(2) Type of ceilings—open or closed.

(3) Finish of ceilings; for example—cement plaster, metal, marine plywood, cement, asbestos board, etc.

(4) Finish of walls; for example—cement plaster, glazed tile, glaze brick, glass blocks, etc.

(5) Screens—indicate whether all outside openings are screened or provided with other suitable devices against entrance of flies or other insects.

(6) Finish of floors—concrete, brick, mastic material, etc.

(7) Drainage—indicate the amount of slope of floors to the drains in processing rooms, coolers, toilets, and refuse rooms, and give description of trapping and venting of drainage lines and of floor drain openings. Indicate size of drainage lines and whether house drainage lines and toilet soil lines are separate to a point outside of buildings.

(8) Heating—indicate type.

(9) Water supply—indicate whether public or private water supply, or both, and specify in terms of gallons of water available per minute for the processing needs of the plant. Also indicate whether or not a nonpotable water supply is used for any purpose in the plant and, if so, specify such uses.

(10) Hot water facilities—specify facilities such as boilers, storage tanks, mixing valves, etc., and indicate the size and number of boilers and storage tanks.

(11) Specify number of men and number of women who will use each toilet room.

(12) Sewage disposal—indicate whether city sewer, cesspool, sedimentation tank, etc.

(13) Approximate rate of production—indicate hourly rate of slaughter and evisceration for rabbits.

(e) Rooms and compartments which must be included in the official plant. The official plant shall include employees' toilet and dressing rooms, office space for the inspectors, storerooms for supplies, refuse rooms, and rooms, compartments, or passageways where rabbits or any ingredients to be used in the preparation of products under inspection will be handled or kept. It also may include other rooms or compartments located in the buildings comprising the official plant.

(f) Changes in drawings or blueprints. When changes are proposed in areas for which drawings or blueprints have been previously approved, one of the following types of revised drawings or blueprints shall be submitted for review and consideration.

(1) A completely revised sheet or sheets showing proposed alterations or additions, or

(2) Approved pasters of the proposed changes which may be affixed to the affected areas on the previously approved drawings or blueprints in a manner not obscuring essential data. Paster drawings and blueprints shall be prepared to the same scale and presented on a background similar to that of the originally approved drawing or blueprint.

(g) Final survey and plant approval. Prior to the inauguration of the inspection service, a final survey of the plant and premises shall be made by the area supervisor or his assistant to determine if the plant is constructed and facilities are installed in accordance with the approved drawings and the regulations in this part. The plant may be approved by the Administrator only when these requirements have been met, except that conditional approval for a specified limited time may be granted only under emergency conditions of restricted availability of facilities and construction materials, provided practices suitable to the Administrator are employed to effect adequate sanitary conditions in the plant.

(Approved by the Office of Management and Budget under control number 0583–0036)

[41 FR 23702, June 11, 1976, as amended at 47 FR 746, Jan. 7, 1982]

§ 354.35 Rejection of application.

Any application for inspection service may be rejected by the Administrator:

(a) Whenever the applicant fails to meet the requirements of the regulations prescribing the conditions under which the service is made available;

(b) Whenever the product is owned by or located on the premises of a person currently denied the benefits of the Act;

(c) Where any individual holding office or a responsible position with or having a substantial financial interest or share in the applicant is currently denied the benefits of the Act or was responsible in whole or in part for the current denial of the benefits of the Act to any person;

(d) Where the Administrator determines that the application is an attempt on the part of a person currently denied the benefits of the Act to obtain inspection service;

(e) Whenever the applicant, after an initial survey has been made in accordance with § 354.34(a), fails to bring the plant, facilities, and operating procedures into compliance with the regulations within a reasonable period of time; or

(f) Notwithstanding any prior approval whenever, before inauguration of service, the applicant fails to fulfill commitments concerning the inauguration of the service. Each such applicant shall be promptly notified by registered mail of the reasons for the rejection. A written petition for reconsideration of such rejection may be filed by the applicant with the Administrator if postmarked or delivered within 10 days after the receipt of notice of the rejection. Such petition shall state specifically the errors alleged to have been made by the Administrator in rejecting the application. Within 20 days following the receipt of such a petition for reconsideration, the Administrator shall approve the application or notify the applicant by registered mail of the reasons for the rejection thereof.

§ 354.36 Withdrawal of application.

Any application for inspection service may be withdrawn by the applicant at any time before the service is performed upon payment, by the applicant, of all expenses incurred by the Service in connection with such application.

§ 354.38 Suspension of plant approval.

(a) Any plant approval given pursuant to the regulations in this part may be suspended by the Administrator for:

(1) Failure to maintain plant and equipment in a satisfactory state of repair;

(2) The use of operating procedures which are not in accordance with the regulations in this part; or

(3) Alterations of buildings, facilities, or equipment which cannot be approved in accordance with the regulations in this part.

(b) During such period of suspension, inspection service shall not be rendered. However, the other provisions of the regulations pertaining to providing service on a resident basis will remain in effect unless such service is terminated in accordance with the provisions of this part. If the plant facilities or methods of operation are not brought into compliance within a reasonable period of time, to be specified by the Administrator, the service shall be terminated. Upon termination of inspection service in an official plant pursuant to the regulations in this part, the plant approval shall also become terminated, and all labels, seals, tags or packaging material bearing official identification shall, under the supervision of a person designated by the Service, either be destroyed, or the official identification completely obliterated, or sealed in a manner acceptable to the Service.

VIOLATIONS

§ 354.45 Denial of service.

(a) The acts or practices set forth in §§ 354.46 through 354.51 or the causing thereof may be deemed sufficient cause, for the debarment, by the Secretary, of any person, including any agents, officers, subsidiaries, or affiliates of such person, from any or all benefits of the Act for a specified period after notice and opportunity for hearing has been afforded.

(b) Whenever the Administrator has reason to believe that any person or his

employee, agent, or representative has flagrantly or repeatedly committed any of the acts or practices specified in §§ 354.46 to 354.51, he may, without hearing, direct that the benefits of the Act be denied such person, including any agents, officers, subsidiaries, or affiliates of such person, pending investigation and hearing, and shall give notice thereof to any such person in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)). The Administrator's decision to deny the benefits of the Act to any such person, including any agents, officers, subsidiaries, or affiliates of such person, shall be effective upon service of such notice. A written petition for reconsideration of such interim denial may be filed with the Administrator by any person so denied the benefits of the Act within 10 days after notice of the interim denial. Such petition shall state specifically the errors alleged to have been made by the Administrator in denying the benefits of the Act pending investigation and hearing. Within 20 days following the receipt of such petition for reconsideration, the Administrator shall reinstate the benefits of the Act or notify the petitioner of the reasons for continued interim denial.

[41 FR 23702, June 11, 1976, as amended at 43 FR 11148, Mar. 17, 1978]

§ 354.46 Misrepresentation; deceptive or fraudulent acts or practices.

Any willful misrepresentation or any deceptive or fraudulent act or practice made or committed by any person in connection with:

(a) The making or filing of any application for any inspection service;

(b) The making of the product accessible for inspection;

(c) The making, issuing, or using, or attempting to issue or use any inspection certificate, symbol, stamp, label, seal or identification, authorized pursuant to the regulations in this part;

(d) The use of the terms ''U.S. Inspected'' or ''Government Inspected'', or any term of similar import in the labeling or advertising of any product.

§ 354.47 Use of facsimile forms.

Using or attempting to use a form which simulates, in whole or in part, any certificate, symbol, stamp, label, seal or identification authorized to be issued or used under the regulations in this part.

§ 354.48 Willful violation of the regulations.

Any willful violation of the regulations in this part or the Act.

§ 354.49 Interfering with an inspector or employee of Service.

Any interference with or obstruction or any attempted interference or obstruction of or assault upon any inspector or employee of the Service in the performance of his duties. The giving or offering directly or indirectly of any money, loan, gift, or anything of value to an employee of the Service or the making or offering of any contribution to or in any way supplementing the salary, compensation, or expenses of an employee of the Service, or the offering or entering into a private contract or agreement with an employee of the Service for any services to be rendered while employed by the Service.

§ 354.51 Miscellaneous.

The existence of any of the conditions set forth in § 354.35 constituting a basis for the rejection of an application for inspection service.

OTHER APPLICABLE REGULATIONS

§ 354.53 Other applicable regulations.

Compliance with the regulations in this part shall not excuse failure to comply with any other Federal or any State or municipal applicable laws or regulations.

IDENTIFYING AND MARKING PRODUCTS

§ 354.60 Approval of official identification.

(a) Any label or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe. No label or packaging material bearing official identification may be used unless finished copies or samples of such labels and packaging material have been approved by the Administrator. No label bearing official identification

shall be printed for use until the printer's final proof has been approved by the Administrator, and no label, other than labels for shipping containers or containers for institutional packs, bearing any official identification shall be used until finished copies or samples of such labels have been approved by the Administrator. Final approval may be given to printer's final proof or photostatic copies of labels for shipping containers or containers for institutional packs, and no such labels shall be used until such proofs or copies have been approved by the Administrator. A label which bears official identification shall not bear any statement that is false or misleading, and if labels in the name of the same packer or distributor, or bearing the same brand name, are used on the same or similar products which are prepared from products which are not inspected, the diameter of the inspection mark used on labels for inspected products shall be equal to at least one-tenth of the length of the label, plus at least one-tenth of the width of the label. If the labeling is printed or otherwise applied directly to the container, the principal display panel of such container shall, for this purpose, be considered as the label.

§ 354.62 Inspection mark with respect to product.

The Administrator is authorized to prescribe and approve the form of the inspection mark that may be used.

§ 354.63 Marking inspected products.

(a) *Wording and form of inspection mark.* Except as otherwise authorized, the inspection mark permitted to be used with respect to inspected and certified edible products shall include wording as follows: ''Inspected for Wholesomeness by U.S. Department of Agriculture.'' This wording shall be contained within a circle in the form and arrangement shown in § 354.65. The appropriate plant number of the official plant shall be included in the circle unless it appears elsewhere on the packaging material. The Administrator may approve the use of abbreviations of such inspection mark, and such approved abbreviations shall have the same force and effect as the inspection mark. The inspection mark or approved abbreviation thereof, as the case may be, may be applied to the inspected and certified edible product or to the packaging material of such product. When the inspection mark, or the approved abbreviation thereof, is used on packaging material, it shall be printed on such material or on a label to be affixed to the packaging material and the name of the packer or distributor of such product shall be printed on the packaging material or label, as the case may be, except that on shipping containers and containers for institutional packs, the inspection marks may be stenciled on the container and, when the inspection mark is so stenciled, the name and address of the packer or distributor may be applied by the use of a stencil or a rubber stamp. Notwithstanding the foregoing, the name and address of the packer or distributor, if appropriately shown elsewhere on the packaging material, may be omitted from insert labels which bear an official identification if the applicable plant number is shown.

(b) *Wording on labels.* Each trade label to be approved for use pursuant to §§ 354.60 to 354.64 with respect to any inspected and certified edible product shall bear the true name of the edible product, the name and address of the packer or distributor thereof, and in prominent letters and figures of uniform size, the inspection mark, as aforesaid, and the label shall also bear, in such manner as may be prescribed or approved by the Administrator, the plant number, if any, of the official plant in which such product was inspected and certified. The class of the rabbits shall be shown on the label. The appropriate designation ''young'', ''mature'', or ''old'' may be used as a prefix to the word ''rabbit'' in lieu of the class name.

(c) *Labels in foreign languages.* Any trade label to be affixed to a container of any edible products for foreign commerce may be printed in a foreign language. However, the inspection mark shall appear on the label in English, but, in addition, may be literally translated into such foreign language. Each such trade label which is to be printed in a foreign language must be approved pursuant to §§ 354.60 to 354.64.

(d) *Unauthorized use or disposition of approved labels.* (1) Labels approved for use pursuant to §§ 354.60 to 354.64 shall be used only for the purpose for which approved and shall not otherwise be disposed of from the plant for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labels or labels bearing official identification may result in cancellation of the approval and denial of the use of labels bearing official identification or denial of the benefits of the Act pursuant to the provisions of § 354.60.

(2) The use of simulations or imitations of any official identification by any person is prohibited.

(e) *Rescindment of approved labels.* Once a year, or more often if requested, each applicant shall submit to the Administrator a list in triplicate of approved labels that have become obsolete, accompanied with a statement that such approvals are no longer desired. The approvals shall be identified by the date of approval and the name of product or other designation showing the class of material.

§ 354.64 Form of official identification.

The form prescribed in § 354.65 is subject to the requirements of §§ 354.60 to 354.64, Identifying and Marking Products.

§ 354.65 Form of inspection mark.

The inspection mark approved for use on inspected and certified edible products shall be contained within a circle and include the following wording: ''Inspected for Wholesomeness by U.S. Department of Agriculture.'' The form and arrangement of such wording shall be as indicated in the example below. The plant number of the official plant shall be set forth if it does not appear on the packaging material.

SUPERVISION OF MARKING AND PACKAGING

§ 354.70 Evidence of label approval.

No inspector shall authorize the use of official identification for any inspected product unless he has on file evidence that such official identification or packaging material bearing such official identification has been approved in accordance with the provisions of §§ 354.60 to 354.64.

§ 354.71 Affixing of official identification.

(a) No official identification or any abbreviation, copy, or representation thereof may be affixed to or placed on or caused to be affixed to or placed on any product or container thereof except by an inspector or under the supervision of an inspector. All such products shall have been inspected and certified. The inspector shall have supervision over the use and handling of all material bearing any official identification.

(b) Each container of inspected and certified products to be shipped from one official plant to another official plant for further processing shall be marked for identification and shall show the following information:

(1) The name of the inspected and certified products in the container;

(2) The name and address of the packer or distributor of such products;

(3) The net weight of the container;

(4) The inspection mark permitted to be used pursuant to the regulations in this part unless the containers are

sealed or otherwise identified in such manner as may be approved by the Administrator; and

(5) The plant number of the official plant where the products were packed.

§ 354.72 Packaging.

No container which bears or may bear any official identification or any abbreviation or copy or representation thereof may be filled in whole or in part except with edible products which were inspected and certified and are, at the time of such filing, sound, wholesome, and fit for human food. All such filling of containers shall be under the supervision of an inspector.

§ 354.73 Retention labels.

An inspector may use such labels, devices, and methods as may be approved by the Administrator for the identification of:

(a) Products which are held for further examination, and

(b) All equipment and utensils which are to be held for proper cleaning.

§ 354.74 Prerequisites to inspection.

Inspection of products shall be rendered pursuant to the regulations in this part and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

§ 354.75 Accessibility of products.

Each product for which inspection service is requested shall be so arranged so as to permit adequate determination of its class, quantity, and condition as the circumstances may warrant.

§ 354.76 Time of inspection in an official plant.

The inspector who is to perform the inspection in an official plant shall be informed, in advance, by the applicant of the hours when such inspection is desired. Inspectors shall have access at all times to every part of any official plant to which they are assigned.

REPORTS

§ 354.90 Report of inspection work.

Reports of the work of inspection carried on within official plants shall be forwarded to the Administrator by the inspector in such manner as may be specified by the Administrator.

§ 354.91 Information to be furnished to inspectors.

When inspection service is performed within an official plant, the applicant for such inspection shall furnish to the inspector rendering such service such information as may be required for the purposes of §§ 354.90 to 354.92.

(Approved by the Office of Management and Budget under control number 0583–0036)

[41 FR 23702, June 11, 1976, as amended at 47 FR 746, Jan. 7, 1982]

§ 354.92 Reports of violation.

Each inspector shall report, in the manner prescribed by the Administrator, all violations of and noncompliance with the Act and the regulations in this part of which he has knowledge.

FEES AND CHARGES

§ 354.100 Payment of fees and charges.

(a) Fees and charges for any inspection shall be paid by the applicant for the service in accordance with the applicable provisions of §§ 354.100 to 354.110, both inclusive. If so required by the inspector, such fees and charges shall be paid in advance.

(b) Fees and charges for any inspection service shall, unless otherwise required pursuant to paragraph (c) of this section, be paid by check, draft, or money order payable to the Food Safety and Inspection Service and remitted promptly to the Service.

(c) Fees and charges for any inspection pursuant to a cooperative agreement with any State or person shall be paid in accordance with the terms of such cooperative agreement.

§ 354.101 On a fee basis.

(a) Unless otherwise provided in this part, the fees to be charged and collected for any service performed, in accordance with this part, on a fee basis shall be based on the applicable rates specified in this section.

(b) The charges for inspection service will be based on the time required to perform such services. The hourly rates shall be as specified in §§ 391.2 and 391.3

respectively for base time and for overtime or holiday work.

(c) Charges for certain laboratory analysis or laboratory examination of rabbits under this part related to inspection service shall be at the rate specified in § 391.4 for that part which is not covered under the base time, overtime, and/or holiday costs.

[41 FR 23702, June 11, 1976, as amended at 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 354.105 Fees for additional copies of inspection certificates.

Additional copies, other than those provided for in §§ 354.141, 354.142, and 354.143, of any inspection certificates may be supplied to any interested party upon payment of a fee of $2.00 for each set of five or fewer copies.

§ 354.106 Travel expenses and other charges.

Charges are to be made to cover the cost of travel and other expenses incurred by the Service in connection with rendering inspection service. Such charges shall include the costs of transportation, per diem, and any other expenses.

§ 354.107 Continuous inspection performed on a resident basis.

The charges for inspection of rabbits and products thereof shall be those provided for in § 354.101(b) and specified by hourly rates in §§ 391.2 and 391.3 when the inspection service is performed on a continuous year-round resident basis and the services of an inspector or inspectors are required 4 or more hours per day. When the services of an inspector are required on an intermittent basis, the charges shall be those provided for in § 354.101(b) and specified by hourly rates in §§ 391.2 and 391.3 plus the travel expense and other charges provided for in § 354.106.

[54 FR 6390, Feb. 10, 1989]

§ 354.109 Fees or charges for inspection service performed under cooperative agreement.

Fees or charges to be made to an applicant for any inspection service which differ from those listed in §§ 354.100 through 354.107 shall be provided for by a cooperative agreement.

§ 354.110 Disposition of fees for inspection made under cooperative agreement.

Fees for inspection under a cooperative agreement with any State or person shall be disposed of in accordance with the terms of such agreement. Such portion of the fees collected under a cooperative agreement as may be due the United States shall be remitted to the Service.

INSPECTION PROCEDURES; ANTE-MORTEM INSPECTIONS

§ 354.120 Manner of handling products in an official plant.

Unless otherwise specified in the regulations in this part or by the Administrator, products which are to be further processed under inspection in an official plant shall be prepared and handled in such official plant under the supervision of an inspector.

§ 354.121 Ante-mortem inspection.

An ante-mortem inspection of rabbits shall, where and to the extent considered necessary by the Administrator and under such instructions as he may issue from time to time, be made of rabbits on the day of slaughter in any official plant processing rabbits under inspection pursuant to the regulations in this part.

§ 354.122 Condemnation on ante-mortem inspection.

Rabbits found in a dying condition on premises of an official plant shall be immediately destroyed and, together with any rabbits found dead on such premises, shall be disposed of in accordance with § 354.132. Rabbits plainly showing, on ante-mortem inspection, any disease or condition, that under §§ 354.129 to 354.131, inclusive, would cause condemnation of their carcasses on post-mortem inspection, shall be condemned. Rabbits which, on ante-mortem inspection, are condemned shall not be dressed, nor shall they be conveyed into any department of the plant where rabbit products are prepared or held. Rabbits which have been condemned on ante-mortem inspection and have been killed shall, under the

supervision of an inspector of the Inspection Service, receive treatment as provided in § 354.132.

§ 354.123 Segregation of suspects on ante-mortem inspection.

All rabbits which, on ante-mortem inspection, do not plainly show, but are suspected of being affected with any disease or condition that under §§ 354.129 to 354.131, inclusive, may cause condemnation in whole or in part on post-mortem inspection, shall be segregated from the other rabbits and held for separate slaughter, evisceration, and post-mortem inspection. The inspector shall be notified when such segregated lots are presented for post-mortem inspection and inspection of such rabbits shall be conducted separately. Such procedure for the correlation of ante-mortem and post-mortem findings by the inspector, as may be prescribed or approved by the Administrator, shall be carried out.

§ 354.124 Quarantine of diseased rabbits.

If live rabbits, which are affected by any contagious disease which is transmissible to man, are brought into an official establishment, such rabbits shall be segregated. The slaughtering of such rabbits shall be deferred and they shall be dealt with in one of the following ways:

(a) If it is determined by a veterinary inspector that further handling of the rabbits will not create a health hazard, the lot shall be subject to ante-mortem and post-mortem inspection pursuant to the regulations in this part.

(b) If it is determined by a veterinary inspector that further handling of the rabbits will not create a health hazard, such rabbits may be released for treatment under the control of an appropriate State or Federal agency. If the circumstances are such that release for treatment is impracticable, a careful rabbit-by-rabbit ante-mortem inspection shall be made, and all rabbits found to be, or which are suspected of being, affected with the contagious disease transmissible to man shall be condemned.

POST-MORTEM INSPECTION

§ 354.125 Evisceration.

No viscera or any part thereof shall be removed from any rabbits which are to be processed under inspection in any official plant, except at the time of evisceration and inspection. Each carcass to be eviscerated shall be opened so as to expose the organs and the body cavity for proper examination by the inspector and shall be prepared immediately after inspection as ready-to-cook rabbit.

§ 354.126 Carcasses held for further examination.

Each carcass, including all parts thereof, in which there is any lesion of disease or other condition, which might render such carcass or any part thereof unfit for human food, and with respect to which a final decision cannot be made on first examination by the inspector, shall be held for further examination. The identity of each such carcass, including all parts thereof, shall be maintained until a final examination has been completed.

§ 354.127 Condemnation and treatment of carcasses.

Each carcass, or any part thereof, which is found to be unsound, unwholesome, or otherwise unfit for human food shall be condemned by the inspector and shall receive such treatment, under the supervision of the inspector, as will prevent its use for human food and preclude dissemination of disease through consumption by animals.

§ 354.128 Certification of carcasses.

Each carcass and all parts and organs thereof which are found by the inspector to be sound, wholesome, and fit for human food shall be certified as provided in this part.

DISPOSITION OF DISEASED RABBIT CARCASSES AND PARTS

§ 354.129 General.

The carcasses or parts of carcasses of all rabbits inspected at an official establishment and found at the time of post-mortem inspection, or at any subsequent inspection, to be affected with any of the diseases or conditions

named in other sections in this part, shall be disposed of in accordance with the section pertaining to the disease or condition. Owing to the fact that it is impracticable to formulate rules for each specific disease or condition and to designate at just what stage a disease process results in an unwholesome product, the decision as to the disposal of all carcasses, parts, or organs not specifically covered by the regulations, or by instructions of the Administrator issued pursuant thereto, shall be left to the inspector in charge, and if the inspector in charge is in doubt concerning the disposition to be made, specimens from such carcasses shall be forwarded to the laboratory for diagnosis.

§ 354.130 Diseases or conditions evident which require condemnation.

(a) Carcasses of rabbits affected with or showing lesions of any of the following named diseases or conditions shall be condemned: Tularemia, anthrax, hemorrhagic septicemia, pyemia, septicemia, leukemia, acute enteritis, peritonitis, sarcomatosis, metritis, necrobacillosis (Smorl's Disease), tuberculosis, emaciation, streptobacillary pseudotuberculosis, and advanced stages of snuffles. Rabbits from pathological laboratories shall be condemned.

(b) Any organ or part of a rabbit carcass affected with a tumor shall be condemned and when there is evidence that the general condition of the rabbit has been affected by the size, position, or nature of the tumor, the whole carcass shall be condemned. In cases of malignant neoplasms involving any internal organ to a marked extent, or affecting the muscles, skeleton, or body lymph glands, even primarily, the whole carcass shall be condemned.

(c) Carcasses of rabbits showing any disease such as generalized melanosis, pseudoleukemia, and the like, which systemically affect the rabbit, shall be condemned.

(d) Any organ or part of a carcass which is badly bruised or which is affected by an abscess, or a suppurating sore, shall be condemned. Parts or carcasses which are contaminated by pus shall be condemned.

(e) Carcasses of rabbits contaminated by volatile oils, paints, poisons, gases, or other substances which affect the wholesomeness of the carcass shall be condemned.

(f) All carcasses of rabbits so infected that consumption of the meat or meat food products thereof may give rise to meat poisoning shall be condemned. This includes all carcasses showing signs of any of the following diseases: Acute inflammation of the lungs, pleura, pericardium, peritoneum or meninges; septicemia or pyemia, whether traumatic, or without evident cause; gangrenous or severe hemorrhagic enteritis or gastritis; polyarthritis and acute nephritis. Immediately after the slaughter of any rabbit so infected, the infected premises and implements used shall be thoroughly sanitized. The part or parts of any carcass coming into contact with the carcass or any part of the carcass of any rabbit covered by this section other than those affected with acute inflammation of the lungs, pleura, pericardium, peritoneum or meninges, shall be condemned.

(g) Carcasses showing any degree of icterus with a parenchymatous degeneration of organs, the result of infection or intoxication, and those which, as a result of a pathological condition, show an intense yellow or greenish-yellow discoloration without evidence of infection or intoxication shall be condemned.

(h) Carcasses of rabbits affected with mange or scab in advanced stages, or showing emaciation or extension of the inflammation to the flesh, shall be condemned. When the diseased condition is slight, the carcass may be passed for food after removal and condemnation of the affected parts.

(i) In the disposal of carcasses and parts of carcasses showing evidence of infestation with parasites not transmissible to man, the following general rules shall govern: If the lesions are localized in such manner and are of such character that the parasites and the lesions caused by them may be radically removed, the non-affected portion of the carcass, or part of the carcass, may be certified for food after the removal and condemnation of the affected portions. Where a part of a carcass shows

numerous lesions caused by parasites, or the character of the infestation is such that complete extirpation of the parasites and lesions is difficult and uncertainly accomplished, or if the parasitic infestation or invasion renders the organ or part in any way unfit for food, the affected organ or part shall be condemned. Where parasites are found to be distributed in a carcass in such a manner or to be of such a character that their removal and the removal of the lesions caused by them are impracticable, no part of the carcass shall be certified for food and the entire carcass shall be condemned. Carcasses infested with a hydatid cyst or cysts (Echinococcus granulosis), transmissible to dogs and from dogs to man, shall in all cases be condemned regardless of the degree of infestation.

(j) Carcasses of rabbits showing such degree of emaciation or anemic condition as would render the meat unwholesome, and carcasses which show a slimy degeneration of the fat or a serious infiltration of the muscles shall be condemned.

§ 354.131 Decomposition.

Carcasses of rabbits deleteriously affected by post-mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) [Reserved]

(c) Carcasses affected by types of post-mortem change which are superficial in nature may be certified for food after removal and condemnation of affected parts.

§ 354.132 Disposal of condemned carcasses and parts.

All condemned carcasses, or parts of carcasses, shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service: (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishment.)

(a) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat for a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. Tanks and equipment used for this purpose or for rendering or preparing inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection, by means of pipes or otherwise, between tanks containing inedible products and those containing edible products.

(b) Incineration or complete destruction by burning.

(c) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(1) Crude carbolic acid,

(2) Kerosene, fuel oil, or used crank case oil,

(3) Any phenolic disinfectant conforming to commercial standards CS 70–41 or CS 71–41 which shall be used in at least 2 percent emulsion or solution, or

(4) Any other substance that the Administrator approves which will decharacterize the carcasses or parts to the extent necessary to accomplish the purposes of this section.

Reinspection and Ingredients

§ 354.133 Reinspection of edible products; ingredients.

(a) Any inspected and certified edible product may be brought into an official plant only if the container of such product is marked for identification in the manner prescribed in § 354.71(b) and the product is reinspected by an inspector at the time it is brought into such plant. Upon reinspection, if any such product or portion thereof is found to be unsound, unwholesome, or otherwise unfit for human food, such product, or portion thereof, shall be condemned and shall receive treatment as provided in § 354.127.

(b) Any product which is prepared under inspection in an official plant shall be inspected in such plant as often as the inspector deems it necessary in order to ascertain whether such product is sound, wholesome, and fit for human food at the time such product leaves such plant. Upon any

such inspection, if any such product or portion thereof is found to be unsound, unwholesome, or otherwise unfit for human food, such product or portion thereof shall be condemned and shall receive treatment as provided in § 354.127.

(c) All substances and ingredients used in the manufacture or preparation of any edible product shall be clean, sound, wholesome, and fit for human food. Liquid and frozen egg products used in the preparation of any edible product shall have been prepared under continuous inspection of the Department.

APPEALS

§ 354.134 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided*, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal. Review of such appeal findings, when requested, shall be made by the immediate superior of the employee of the Department making the appeal inspection. The cost of any such appeal shall be borne by the applicant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be based on the hourly rates as specified in § 354.101(b).

INSPECTION CERTIFICATES

§ 354.140 Forms of inspection certificates.

Each inspection certificate issued pursuant to the regulations in this part shall be approved by the Administrator as to form, and:

(a) Each rabbit inspection certificate shall show the class or classes of rabbits, the quantity of product contained in the respective lot, and all pertinent information concerning the condition and wholesomeness thereof;

(b) Each food product inspection certificate shall show the names of the edible products covered by such certificate, the quantity of each such product, such shipping marks as are necessary to identify such products, and all pertinent information concerning the condition and wholesomeness thereof;

(c) Each export certificate shall show the respective names of the exporter and the consignee, the destination, the shipping marks, the numbers of the export stamps attached to the edible products to be exported and covered by the certificate, and the names of such products and the total net weight thereof.

§ 354.141 Issuance and disposition of rabbits inspection certificates.

(a) Upon the request of an interested party, any inspector is authorized to issue a rabbit inspection certificate with respect to any lot of rabbits inspected by him. Each certificate shall be signed by the inspector who made the inspection covered by the certificate, and if more than one inspector participated in the inspection of the lot of rabbits, each such inspector shall sign the certificate with respect to such lot.

(b) The original and a copy of each inspection certificate, issued pursuant to §§ 354.140 to 354.144, and not to exceed two additional copies thereof if requested by the applicant prior to issuance, shall, immediately upon issuance, be delivered or mailed to the applicant or person designated by him. One copy shall be filed in the office of the area supervisor serving the area in which the inspection was performed, and the remaining copies shall be disposed of in such manner as the Administrator may approve. Additional copies of any such certificate may be furnished to any interested party as provided in § 354.105.

§ 354.142 Food product inspection certificates; issuance and disposition.

(a) Upon the request of an interested party, any inspector is authorized to issue a food product inspection certificate with respect to any inspected and certified edible product after suitable examination of the product has been made by the inspector.

(b) The original of each food product inspection certificate, and not to exceed two copies thereof, if requested,

shall, immediately upon issuance, be delivered or mailed to the applicant or person designated by him. Another copy shall be filed in the office of the regional supervisor serving the area in which such certificate was issued, and one copy shall be forwarded to the Administrator. The last named two copies shall be retained until otherwise ordered by the Administrator.

§ 354.143 Export certificates; issuance and disposition.

(a) Upon the request of an exporter, any inspector is authorized to issue an export certificate with respect to the shipment to any foreign country of any inspected and certified edible product after suitable examination of the product has been made by the inspector.

(b) Each export certificate shall be issued in quintuplicate; the original shall be delivered to the exporter who requested such certificate, and the duplicate copy shall be delivered to the agent of the railroad or other carrier transporting such products from the United States. The triplicate copy of such export certificate shall be forwarded to the Administrator; the quadruplicate copy shall be filed in the office of the regional supervisor serving the area in which such export certificate was issued, and the memorandum copy shall be retained by the inspector for filing. The last named three copies shall be retained until otherwise ordered by the Administrator.

§ 354.144 Advance information.

Upon the request of an applicant, all or part of the contents of any inspection certificate issued to such applicant may be telephoned or telegraphed to him, or to any person designated by him, at his expense.

Basis of Acceptability of Other Official Inspection Systems

§ 354.160 General.

Any rabbit inspection system may be deemed to be acceptable to the Administrator which:

(a) Is conducted under the authority of laws, ordinances, or similar enactments of the State, county, city, or other political subdivision in which is located the official plant at which the ready-to-cook rabbits are prepared and

(b) Imposes at least the requirements set forth in § 354.161: *Provided,* That no such inspection shall be deemed acceptable to the Administrator with respect to any official plant in which ready-to-cook rabbits are prepared if he finds at any time that such requirements are not adequately enforced.

§ 354.161 Requirements as to manner of inspection.

(a) The inspection shall be conducted by an inspector who is a qualified veterinarian or under the supervision of a qualified veterinarian. All such inspectors shall be employed by the State, county, city, or other political subdivision in which the official plant is located.

(b) The inspection shall include post-mortem examination of each rabbit carcass during the evisceration operation.

(c) All carcasses which show evidence of disease or any other condition which may render them unwholesome or unfit for food shall be condemned and shall be destroyed for food purposes under the supervision of an inspector. Each carcass and part thereof which has been inspected and passed or containers of carcasses or parts thereof shall bear the identifying inspection symbol of the official inspection system and the marking devices or labels shall be in the custody of the inspector at all times.

§ 354.162 Determining compliance with § 354.161.

A qualified veterinary supervisor of the rabbit inspection service shall investigate the manner of operation of the inspection system to determine the adequacy of the post-mortem examination and the compliance with the requirements contained in §§ 354.160 to 354.162 prior to approving the official plant for the inspection of ready-to-cook rabbits. This supervisor, as well as any official graders who may be stationed in the official plant, shall periodically observe the inspection operations in the official plant to determine that the requirements of §§ 354.160 to 354.162 are being met.

SANITARY REQUIREMENTS

GENERAL

§ 354.210 Minimum standards for sanitation, facilities, and operating procedures in official plants.

The provisions of §§ 354.210 to 354.247 shall apply with respect to inspection service in all official plants. The table set forth in § 354.247 indicates some of the types of material which may be used in the construction of equipment, utensils, and facilities for use in the plant.

BUILDINGS AND PLANT FACILITIES

§ 354.220 Buildings.

The buildings shall be of sound construction and kept in good repair, and shall be of such construction as to prevent the entrance or harboring of vermin.

(a) *Outside openings.* (1) The doors, windows, skylights, and other outside openings of the plant, except receiving rooms and live rabbit holding rooms, shall be protected by properly fitted screens or other suitable devices against the entrance of flies and other insects.

(2) Outside doors, except in receiving rooms and live rabbit holding rooms, shall be self-closing and so hung that not over ¼–inch clearance remains when closed. Screen doors shall open toward the outside of the building.

§ 354.221 Rooms and compartments.

Rooms and compartments used for edible products shall be separate and distinct from inedible products departments and from rooms where rabbits are slaughtered and skinned. Separate rooms shall be provided when required for conducting processing operations in a sanitary manner, and all rooms shall be of sufficient size to permit the installation of the necessary equipment for processing operations and the conduct of such operations in a sanitary manner.

(a) *Rooms for separate operation.* The official plant should have separate rooms for each of the following operations depending upon the various types of operations conducted, but, in no case, shall the receiving or holding of live rabbits or killing operations be permitted in rooms in which eviscerating operations are performed:

(1) The receiving and feeding of live rabbits.

(2) Killing and skinning operations.

(3) Eviscerating, chilling, and packing operations for ready-to-cook rabbits.

(4) Inedible products departments.

(5) Refuse room.

(b) *Rooms for holding carcasses for further inspection.* Rooms and compartments in which carcasses or parts thereof are held for further inspection shall be in such number and such location as the needs of the inspection in the plant may require. They shall be equipped with locks and keys and the keys shall not leave the custody of the inspector in charge of the plant. All such rooms and compartments shall be marked conspicuously with the word ''retained'' in letters not less than 2 inches high.

(c) *Coolers and freezers.* Coolers and freezers of adequate size and capacity shall be provided to reduce the internal temperature of ready-to-cook rabbits prepared and otherwise handled in the plant to 36 °F. within 24 hours unless other cooling facilities are available.

(d) *Refuse rooms.* Refuse rooms shall be entirely separate from other rooms in the plant, and shall have tight fitting doors and be properly ventilated.

(e) *Storage and supply rooms.* The storage and supply rooms shall be in good repair, kept dry, and maintained in a sanitary condition.

(f) Boiler room. The boiler room shall be a separate room, if necessary, to prevent its being a source of dirt and objectionable odors entering any room where ready-to-cook rabbits are prepared, processed, handled, and stored.

(g) *Inspector's office.* Furnished office space, including, but not being limited to, light, heat, and janitor service shall be provided rent free in the official plant for the exclusive use for official purposes of the inspector and the Administration. The room or rooms set apart for this purpose must meet with the approval of the regional supervisor and be conveniently located, properly ventilated, and provided with lockers or cabinets suitable for the protection

and storage of supplies and with facilities suitable for inspectors to change clothing.

(h) *Toilet rooms.* Toilet rooms opening directly into rooms where rabbit products are exposed shall have self-closing doors and shall be ventilated to the outside of the building.

§ 354.222 Floors, walls, ceilings, etc.

(a) *Floors.* All floors in rooms where exposed products are prepared or handled shall be constructed of or finished with materials impervious to moisture, so they can be readily and thoroughly cleaned. The floors in killing, ice cooling, ice packing, eviscerating, cooking, boning, and cannery rooms shall be graded for complete runoff with no standing water.

(b) *Walls, posts, partitions, doors.* All walls, posts, partitions, and doors in rooms where exposed products are prepared or handled shall be smooth and constructed of materials impervious to moisture to a height of 6 feet above the floor to enable thorough cleaning. All surfaces above this height must be smooth and finished with moisture-resistant material.

(c) *Ceilings.* Ceilings must be moisture-resistant in rooms where exposed products are prepared or handled, and finished and sealed to prevent collection of dirt or dust that might sift through flooring above or fall from collecting surfaces on equipment or exposed product.

§ 354.223 Drainage and plumbing.

There shall be an efficient drainage and plumbing system for the plant and premises.

(a) *Drains and gutters.* All drains and gutters shall be properly installed with approved traps and vents. The drainage and plumbing system must permit the quick runoff of all water from plant buildings, and surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard.

(b) *Sewage and plant wastes.* (1) The sewerage system shall have adequate slope and capacity to remove readily all waste from the various processing operations and to minimize, and if possible to prevent, stoppage and surcharging of the system.

(2) Grease traps which are connected with the sewerage system shall be suitably located but not near any edible products department or in any area where products are unloaded from or loaded into vehicles. To facilitate cleaning, such traps shall have inclined bottoms and be provided with suitable covers.

(3) Toilet soil lines shall be separate from house drainage lines to a point outside the buildings unless they are positively trapped to prevent backing up. Drainage from toilet bowls and urinals shall not be discharged into a grease catch basin.

(4) All floor drains shall be equipped with traps, constructed so as to minimize clogging, and the plumbing shall be so installed as to prevent sewerage from backing up and from flooding the floor.

(5) Floor drainage lines should be of metal and at least 4 inches in diameter and open into main drains of at least 6 inches in diameter and shall be properly vented to outside air.

(6) Where refrigerators are equipped with drains, such drains should be properly trapped and should discharge through an air gap into the sewer system. All new installations, and all replacements, or refrigerators equipped with drains shall meet these requirements.

§ 354.224 Water supply.

The water supply shall be ample, clean, and potable with adequate facilities for its distribution in the plant and its protection against contamination and pollution.

(a) Hot water at a temperature not less than 180 °F. shall be available for sanitation purposes.

(b) Hose connections with steam and water mixing valves or hot water hose connections shall be provided at convenient locations throughout the plant for cleaning purposes.

(c) The refuse rooms shall be provided with adequate facilities for washing refuse cans and other equipment in the rooms; the rooms, cans, and equipment shall be cleaned after each day's use.

§ 354.225 Lavatory accommodations.

Modern lavatory accommodations and properly located facilities for cleaning utensils and hands shall be provided.

(a) Adequate lavatory and toilet accommodations, including, but not being limited to, running hot water and cold water, soap, and towels, shall be provided. Such accommodations shall be in or near toilet and locker rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products.

(b) Sufficient metal containers shall be provided for used towels and other wastes.

(c) An adequate number of hand washing facilities serving areas where dressed rabbits and edible products are prepared shall be operated by other than hand-operated controls, or shall be of a continuous flow type which provides an adequate flow of water for washing hands.

(d) Durable signs shall be posted conspicuously in each toilet room and locker room directing employees to wash their hands before returning to work.

(e) Toilet facilities shall be provided according to the following formula:

Persons of same sex	Toilet bowls required
1 to 15, inclusive	1
16 to 35, inclusive	2
36 to 55, inclusive	[1] 3
56 to 80, inclusive	[1] 4
For each additional 30 persons in excess of 80	[1] 1

[1] Urinals may be substituted for toilet bowls but only to the extent of 1/3 of the total number of bowls stated.

§ 354.226 Lighting and ventilation.

There shall be ample light, either natural or artificial or both, of good quality and well distributed, and sufficient ventilation for all rooms and compartments to insure sanitary conditions.

(a) All rooms in which rabbits are killed, eviscerated, or otherwise processed shall have at least 30 foot candles of light intensity on all working surfaces except that at the inspection stations such light intensity shall be of 50 foot candles. In all other rooms, there shall be provided at least 5 foot candles of light intensity when measured at distance of 30 inches from the floor.

(b) All rooms shall be adequately ventilated to eliminate objectionable odors and minimize moisture condensation.

EQUIPMENT AND UTENSILS

§ 354.230 Equipment and utensils.

Equipment and utensils used for the preparation, processing, or other handling of any product in the plant shall be suitable for the purpose intended and shall be of such material and construction as will facilitate their thorough cleaning and insure cleanliness in the preparation and handling of products.

(a) Live rabbit holding pens shall be so constructed as to allow satisfactory ante-mortem examination and to permit proper cleaning.

(b) Metal refuse containers shall be provided, and such containers shall be kept covered.

(c) Insofar as it is practical, equipment and utensils shall be made of metal or other impervious material. Trucks and receptacles used for handling inedible products shall be of similar construction and shall be conspicuously and distinctly marked and shall not be used for handling any edible products.

(d) Chilling vats or tanks used for chilling ready-to-cook rabbits shall be made of metal or other hard-surfaced impervious material.

(e) Where grading bins are used for ready-to-cook rabbits, they shall be of sufficient number and capacity to handle the grading adequately without the use of makeshift bins and all ready-to-cook rabbits shall be kept off the floor. Grading bins may be made of metal or enameled wood and shall be constructed and maintained in such a manner as to allow easy and thorough cleaning. All replacements of such bins shall, however, be of metal.

(f) Except as otherwise provided herein, all equipment and utensils used in the killing, skinning, eviscerating, chilling, and packing rooms shall be of metal or other impervious material and constructed so as to permit proper and complete cleaning.

(g) Conveyors: (1) Conveyors used in the preparation of ready-to-cook rabbits shall be of metal or other acceptable material and of such construction as to permit thorough and ready cleaning and easy identification of viscera with its carcass.

(2) Overhead conveyors shall be so constructed and maintained that they do not allow grease, oil, or dirt to accumulate on the drop chain or shackle, which shall be of noncorrosive metal.

(3) Nonmetallic belt-type conveyors used in moving edible products shall be of water-proof composition.

(h) Inspection, eviscerating, and cutting tables shall be made of metal and have coved corners and be so constructed and placed to permit thorough cleaning.

(i) In plants where no conveyors are used, each carcass shall be eviscerated in an individual metal tray of seamless construction.

(j) Water spray washing equipment shall be used for washing carcasses inside and out.

(k) Watertight metal receptacles shall be used for entrails and other waste resulting from preparation of ready-to-cook rabbits.

(l) Watertight trucks and receptacles for holding or handling diseased carcasses and diseased parts of carcasses shall be so constructed as to be readily and thoroughly cleaned; such trucks and receptacles shall be marked in a conspicuous manner with the word ''condemned'' in letters not less than 2 inches high and, when required by the inspector in charge, shall be equipped with facilities for locking and sealing.

(m) Freezing rooms should be adequately equipped to freeze ready-to-cook rabbits solid in less than 48 hours. Ready-to-cook rabbits should be frozen at temperatures of −10 °F. to −40 °F. and should be stored at 0 °F. or below, with the temperature maintained as constant as possible. Freezing room should be equipped with floor racks or pallets and fans to insure air circulation.

(n) Cooling racks should be made of metal and be readily accessible for thorough washing and cleaning. All replacements of cooling racks shall be made of metal.

(o) Trucks and receptacles in which carcasses or parts thereof are held for further inspection shall be in such number and such location as the needs of the inspection in the plant may require. They shall be equipped for locking by means of lock and key and the key shall not leave the custody of the inspector in charge of the plant. Such trucks and receptacles shall be marked conspicuously with the word ''retained'' in letters not less than 2 inches high.

§ 354.231 Accessibility.

All equipment shall be so placed as to be readily accessible for all processing and cleaning operations.

§ 354.232 Restrictions on use.

Equipment and utensils used in the official plant shall not be used outside the official plant except under such conditions as may be prescribed or approved by the national supervisor, and equipment used in the preparation of any article (including, but not being limited to, animal food) from inedible material shall not be used outside of the inedible products department except under such conditions as may be prescribed or approved by the national supervisor.

Maintenance of Sanitary Conditions and Precautions Against Contamination of Products

§ 354.240 General.

The premises shall be kept free from refuse, waste materials, and all other sources of objectionable odors and conditions.

§ 354.241 Cleaning of rooms and compartments.

Rooms, compartments, or other parts of the official plant shall be kept clean and in sanitary condition.

(a) All blood, offal, rabbits or parts of rabbits too severely damaged to be salvaged and all discarded containers and other materials shall be completely disposed of daily.

(b) All windows, doors, and light fixtures in the official plant shall be kept clean.

(c) All docks and rooms shall be kept clean and free from debris and unused equipment and utensils.

(d) Live rabbit receiving docks and receiving rooms shall be of such construction as readily to permit their thorough cleaning, and such docks and rooms should be kept clean at all times.

(e) Floors in live rabbit holding rooms shall be cleaned with such regularity as may be necessary to maintain them in a sanitary condition.

(f) The killing and skinning room shall be kept clean and free from offensive odors at all times.

(g) The walls, floors, and all equipment and utensils used in the killing and skinning room shall be thoroughly washed and cleaned after each day's operation.

(h) The floor in the killing and skinning rooms shall be cleaned frequently during killing and skinning operations and be kept reasonably free from accumulated blood, offal, water, and dirt.

(i) All equipment in the toilet room and locker room, as well as the room itself, shall be kept clean, sanitary, and in good repair.

(j) Cooler and freezer rooms shall be free from objectionable odors of any kind and shall be maintained in a sanitary condition (including, but not being limited to, the prevention of drippings from refrigerating coils onto products).

§ 354.242 Cleaning of equipment and utensils.

Equipment and utensils used for preparing or otherwise handling any product shall be kept clean and in a sanitary condition and in good repair.

(a) Pens shall be cleaned regularly and the manure removed from the plant daily.

(b) All equipment and utensils used in the killing and skinning rooms shall be thoroughly washed and cleaned after each day's operation. The eviscerating, chilling, and packing room and equipment and utensils used therein shall be maintained in a clean and sanitary condition.

(c) Graders' and packers' gloves and grading bins shall be washed daily and used only for grading or packing, as the case may be.

(d) All crates or pens used for transporting live rabbits to the plant shall be cleaned regularly.

(e) Chilling vats or tanks, if practicable, shall be emptied after each use. They shall be thoroughly cleaned once daily and, after each cleaning operation, they shall be sanitized with such compounds or by such methods as may be approved or prescribed by the Administrator.

(f) When synchronized overhead conveyors and tray conveyors are used, the trays shall be completely washed and sanitized after being automatically emptied of inedible viscera.

(g) When a conveyor tray operation is used, each carcass shall be eviscerated in an individual metal tray of seamless construction, and such trays shall be completely washed and sanitized after each use.

(h) Tables, shelves, bins, trays, pans, knives, and all other tools and equipment used in the preparation of ready-to-cook rabbits shall be kept clean and sanitary at all times. Cleaned equipment and utensils shall be drained on racks and shall not be nested.

(i) Drums, cans, tanks, vats, and other receptacles used to hold or transport ready-to-cook rabbits shall be kept in a clean and sanitary condition.

§ 354.243 Operations and procedures.

Operations and procedures involving the preparation, storing, or handling of any product shall be strictly in accord with clean and sanitary methods.

(a) There shall be no handling or storing of materials which create an objectionable condition in rooms, compartments, or other places in the plant where any product is prepared, stored, or otherwise handled.

(b) Blood from the killing operation shall be confined to a relatively small area and kept from being splashed about the room.

(c) In the final washing, the carcass shall be passed through a system of sprays providing an abundant supply of fresh clean water.

(d) The floors in the eviscerating room shall be kept clean and reasonably dry during eviscerating operations and free of all refuse.

(e) Conveyors shall be operated at such speeds as will permit a sanitary

eviscerating operation and will permit adequate inspection for condition and wholesomeness.

(f) Mechanized packaging equipment shall be maintained in good sanitary condition.

(g) All offal resulting from the eviscerating operation shall be removed as often as necessary to prevent the development of a nuisance.

(h) Paper and other material used for lining containers in which products are packaged shall be of such kinds as do not tear readily during use, but remain intact when moistened by the product. Wooden containers to be used for packaging ready-to-cook rabbits shall be fully lined except when the individual carcasses to be packaged therein are fully wrapped.

(i) Protective coverings shall be used for the product in the plant and as it is distributed from the plant, as will afford adequate protection for the product against contamination by any foreign substance (including, but not being limited to, dust, dirt, and insects), considering the means intended to be employed in transporting the product from the plant.

(j) Refuse may be moved directly to loading docks only for prompt removal.

(k) Cleanliness and hygiene of personnel: (1) All employees coming in contact with exposed edible products or edible products handling equipment shall wear clean garments and should wear caps or hair nets, and shall keep their hands clean at all times while thus engaged.

(2) Hands of employees handling edible products or edible products handling equipment shall be free of infected cuts, boils, and open sores at all times while thus engaged.

(3) Every person, after each use of toilet or change of garments, shall wash his hands thoroughly before returning to duties that require the handling of edible products or containers therefor or edible products handling equipment.

(4) Neither smoking nor chewing of tobacco shall be permitted in any room where exposed edible products are prepared, processed, or otherwise handled.

§ 354.244 Temperatures and cooling and freezing procedures.

Temperatures and procedures which are necessary for cooling and freezing of rabbits in accordance with sound commercial practice shall be maintained in the coolers and freezers, and chilling temperatures and procedures shall also be in accordance with sound commercial practice.

(a) *Cooling.* Immediately after evisceration and washing of the carcass, it shall be placed in a cooling tank containing running cold tap water to remove the animal heat from the carcass. Carcasses shall not be allowed to remain in the cooling tank for longer than 1 hour.

(b) *Air chilling.* Immediately after the initial water chilling, the carcasses shall be placed in cooling racks and thereupon placed in a refrigerated cooler with moderate air movements and a temperature which will reduce the internal temperature of the carcasses to from 36 °F. to 40 °F., both inclusive, within 24 hours.

(c) *Freezing.* (1) When ready-to-cook rabbits are packaged in bulk or shipping containers, the carcasses should be individually wrapped or packaged in water-vapor resistant cartons or the containers should be lined with heavy water-vapor resistant paper so as to assure adequate overlapping of the lining to completely surround the carcasses and to permit unsealed closure or sealing in such a manner that water-vapor loss from the product is considerably retarded or prevented. The rabbit carcasses should receive an initial rapid freezing under such packaging, temperature, air circulation, and stacking conditions which will result in freezing the carcasses solid in less than 48 hours.

(2) Frozen ready-to-cook rabbits shall be held under conditions which will maintain the product in a solidly frozen state with temperature maintained as constant as possible.

(d) *Refrigeration.* Immediately after packaging, all ready-to-cook rabbits, other than those which are shipped from the plant in a refrigerated carrier, should be moved into the freezer, except that a period not exceeding 72 hours will be permitted for transportation and temporary holding before

placing in the freezer provided such rabbits are held at not above 36 °F.

§ 354.245 Vermin.

Every practicable precaution shall be taken to exclude flies, rats, mice, and other vermin from the official plant. Dogs, cats, and other pets shall be excluded from rooms where edible products are processed, handled, or stored.

§ 354.246 Exclusion of diseased persons.

No person affected with any communicable disease (including, but not being limited to, tuberculosis) in a transmissible stage shall be permitted in any room or compartment where exposed or unpacked edible products are prepared, processed, or otherwise handled.

§ 354.247 Table showing types of materials.

Equipment, utensils, and facilities	Iron	Stainless steel and monel metal	Aluminum	Galvanized iron
Holding pens	A	A	A	A
Overhead conveyors	A	A	A	A
Conveyor track	A	A	.....	A
Shackles	.....	A	.....	A
Shackle chain	A	A	.....	A
Eviscerating pans	.....	A	A	A
Inspection table	.....	A	A	A
Inside and outside washer	.....	A	A	A
Cooling tanks and racks	.....	A	A	A
Utensils for handling edible products	.....	A	A	A
Framework (of equipment)	A			

Key: A—Acceptable.

§ 354.248 Scope and applicability of rules of practice.

The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 354).

[43 FR 11148, Mar. 17, 1978]

PART 355—CERTIFIED PRODUCTS FOR DOGS, CATS, AND OTHER CARNIVORA; INSPECTION, CERTIFICATION, AND IDENTIFICATION AS TO CLASS, QUALITY, QUANTITY, AND CONDITION

DEFINITIONS

SCOPE OF INSPECTION SERVICE

APPLICATION FOR INSPECTION, CERTIFICATION, AND IDENTIFICATION

INAUGURATION OF INSPECTION

FEES

SANITATION AND FACILITIES

INSPECTION PROCEDURE

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 23 FR 10107, Dec. 23, 1958, unless otherwise noted. Redesignated at 30 FR 4195, Mar. 31, 1965.

DEFINITIONS

§ 355.1 Meaning of words.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 355.2 Terms defined.

When used in this part unless otherwise distinctly expressed or manifestly incompatible with the intent thereof:

(a) *Person* means any individual, partnership, association, business trust, corporation, or any organized group of persons, whether incorporated or not.

(b) *Program* means the Meat and Poultry Inspection Program of the Food Safety and Inspection Service of the United States Department of Agriculture.

(c) *Circuit supervisor* means an inspector of the Program assigned to supervise and perform official work at a circuit. Such inspector is assigned by and reports directly to the Administrator or other person designated by him.

(d) *Inspector* means an inspector of the Program.

(e) *Inspected plant* means any plant preparing certified products for dogs, cats, or other carnivora at which inspection is maintained under the regulations contained in this part.

(f) *Circuit* means one or more inspected plants assigned to a circuit supervisor.

(g) *Animal protein supplement* means a product containing animal protein and other elements normal to the component for use in compounding a maintenance food for dogs, cats, and other carnivora.

(h) *Products* means the products for dogs, cats, and other carnivora marked, or to be marked, with the certification provided in this part.

(i) *Meat* means the U.S. inspected and passed and so identified clean, wholesome muscle tissue of cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus with or without the accompanying and overlying fat and the portions of skin, sinews, nerves, and blood vessels which normally accompany the

muscle tissue and which are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears.

(j) *Animal food meat by-product* means the part other than meat which has been derived from one or more cattle, sheep, swine or goats that have been U.S. Inspected and Passed and is fit for use as animal food.

(k) *Horse meat* means the U.S. inspected and passed and so identified clean, wholesome muscle tissue of horses which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without the accompanying and overlying fat and the portions of sinews, nerves, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing.

(l) *Animal food horse meat by-product* means the part other than meat which has been derived from one or more horses that have been U.S. Inspected and Passed and is fit for use as animal food.

(m) *Mule meat* means the clean, sound, healthful, wholesome muscle tissue derived from mules as determined by antemortem and postmortem inspection by an inspector in accordance with §355.41. It includes muscle tissue which is found in the tongue, in the diaphragm, in the heart or in the esophagus, with or without the accompanying and overlying fat and the portions of sinews, nerves, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing.

(n) *Animal food mule meat by-product* means the part other than meat which has been derived from one or more mules that have been handled in accordance with §355.41 and is fit for use as animal food.

(o) *Bone* means the U.S. inspected and passed and so identified clean, wholesome bone which has been derived from cattle, sheep, swine, goats or horses, or bone derived from mules slaughtered and passed under Program inspection in accordance with §355.41.

(p) *Poultry* means any domesticated bird slaughtered in accordance with the Poultry Products Inspection Act, Public Law 85–172, 85th Congress, S. 1747, dated August 28, 1957 (21 U.S.C. 451 *et seq.*).

(q) *Poultry product* means any edible part of fresh poultry which have been slaughtered for human food and from which the blood, feathers, feet, head and viscera have been removed in accordance with rules and regulations promulgated by the Secretary of Agriculture.

(r) *Administrator*. The Administrator of the Food Safety and Inspection Service or any officer or employee of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(s) *Whale meat* means the muscle tissue of whales which is fit for use in animal food.

(t) *Fish* means the whole or part of any aquatic, water breathing vertebrates, commonly designated as fish, which is fit for use in animal food.

(u) *Animal food poultry byproduct* means any portion of carcasses of poultry slaughtered under inspection and passed in accordance with the Poultry Products Inspection Act which is fit for use in animal food.

[23 FR 10107, Dec. 23, 1958, as amended at 25 FR 1356, Feb. 16, 1960; 29 FR 18418, Dec. 25, 1964. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 13115, Sept. 15, 1967; 33 FR 6707, May 2, 1968]

SCOPE OF INSPECTION SERVICE

§ 355.3 Plants eligible for inspection.

Upon application, inspection may be granted at a plant where products are to be prepared, when the Administrator has determined that the application conforms to and the plant meets with the requirements of this part.

APPLICATION FOR INSPECTION, CERTIFICATION, AND IDENTIFICATION

§ 355.4 Application.

The owner or operator of any plant of the kind specified in §355.3 may apply to the Administrator for inspection, certification, and identification. In cases of change of ownership or change

of location, new applications shall be made.

(Approved by the Office of Management and Budget under control number 0583–0036)

[23 FR 10107, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 47 FR 746, Jan. 7, 1982]

§ 355.5 Drawings.

Triplicate copies of complete drawings with specifications, consisting of floor plans showing the locations of such features as the principal pieces of equipment, floor drains, principal drainage lines, hand-washing basins, and hose connections for cleanup purposes; elevations; roof plans when necessary to show size and location of skylights and the like; cross and longitudinal sections of the various buildings, showing such features as principal pieces of equipment, heights of ceilings, conveyor rails, and character of floors, walls, and ceilings; and a plot plan showing relationship of various departments and structures of the plants, properly drawn to scale, shall accompany applications. Where complete approved drawings and specifications are available in the files of the Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, covering a plant operating under the supervision of that Program, it will not be necessary that drawings and specifications accompany an application made under this part for inspection at such plant.

[23 FR 10107, Dec. 23, 1958. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 13115, Sept. 15, 1967]

§ 355.6 Review of applications.

The Administrator will determine whether applications shall be granted or refused.

INAUGURATION OF INSPECTION

§ 355.7 Inauguration of inspection.

When an application for inspection, certification, and identification is granted, the circuit supervisor shall, at or prior to the inauguration of inspection, inform the owner or operator of the plant of the requirements of the regulations contained in this part. Inspection shall not be begun if a plant is not in a sanitary condition. The applicant shall adopt and enforce all necessary measures and shall comply with all such directions as the circuit supervisor may prescribe for carrying out the purposes of this part.

§ 355.8 Official number.

To each plant granted inspection an official number shall be assigned. Such number shall be preceded by the letter ''A'' and used to identify all certified products prepared in the plant.

§ 355.9 Numbers granted same ownership or control.

Two or more official plants under the same ownership or control may be granted the same official number, provided a serial letter is added after the number in each case to identify the plant.

§ 355.10 Assignment of inspectors.

The Administrator shall designate a circuit supervisor of the inspection at each circuit and assign to him such assistants as may be necessary.

FEES

§ 355.11 Charge for survey.

Applicants for the inspection, certification, and identification shall reimburse the department for salary, travel cost, per diem allowance, and the like, expended incidental to any survey of the premises for which the inspection is requested, and in connection with any review of plans which may be made.

§ 355.12 Charge for service.

The fees to be charged and collected by the Administrator shall be at the rates specified in §§ 391.2, 391.3, and 391.4 respectively for base time; for overtime, including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall reimburse the Service for the cost of the inspection service furnished.

[54 FR 6390, Feb. 10, 1989]

SANITATION AND FACILITIES

§ 355.13 Sanitation.

Sanitary facilities and accommodations shall be furnished by every inspected plant. Of these the following are specifically required:

(a) Dressing rooms, toilet rooms, and urinals shall be sufficient in number, ample in size, and conveniently located. They shall be properly lighted and ventilated and of sanitary construction. They shall be separate from the rooms and compartments in which certified products are prepared, stored or handled.

(b) Modern hand-washing basins, including running hot and cold water, soap and towels shall be placed in or near toilet rooms.

(c) Toilet soil lines shall be separate from house drainage lines to a point outside the buildings and drainage from toilet soil lines shall not be discharged into a grease catchbasin.

(d) Properly located facilities shall be provided for cleansing utensils and hands of all persons handling or preparing any products to be certified.

(e) Equipment and utensils used for preparing any products to be certified shall be of such material and construction as will make them susceptible of being readily and thoroughly cleaned.

(f) Trucks and receptacles used for inedible materials shall be of such construction as to permit ready and thorough cleansing, shall bear a conspicuous and distinctive mark, and shall be used exclusively for handling inedible material.

(g) Rooms, compartments, places, equipment and utensils used for preparing, storing or otherwise handling any certified products, and all other parts of the inspected plant, shall be kept clean. There shall be no handling or storing of materials which creates an objectionable condition in rooms, compartments or places where certified products are prepared, stored or otherwise handled.

§ 355.14 Facilities.

Adequate facilities for the preparation and inspection of the products to be certified shall be furnished and maintained by the inspected plant. Of these the following are specifically required:

(a) A room or compartment adequately equipped for locking or sealing shall be provided for holding products prepared for certification or material used in their preparation which are identified as ''U.S. retained,'' and such rooms and compartments shall be conspicuously marked with the phrase ''U.S. retained'' prominently displayed.

(b) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles including carcasses, parts of carcasses and other materials, shall be provided.

(c) Rooms or compartments adequate in size and properly equipped for holding samples of canned products prepared for certification under incubation, shall be maintained at the temperature specified in § 355.25(i).

(d) Furnished office room, including light, heat, janitor, and laundry service shall be provided rent free for the exclusive use of the inspector. These facilities shall be set apart for this purpose and provided with lockers suitable for the protection and storage of program supplies. Laundering of inspectors' outer work clothing shall be provided by the management of inspected plants.

§ 355.15 Inedible material operating and storage rooms; outer premises, docks, driveways, etc.; fly-breeding material; nuisances.

All operating and storage rooms and departments of inspected plants used for inedible material shall be maintained in clean condition, and shall be separate and apart from rooms and departments where certified products are prepared, handled, or stored. Docks and areas where cars and vehicles are loaded, and driveways, approaches and alleyways shall be properly paved and drained and the outer premises of every inspected plant shall be kept in clean and orderly condition. All catchbasins on the premises shall be of such construction and location and shall be given such attention as will insure their being kept in acceptable condition as regards odors and cleanliness. The accumulation on the premises of any material in which flies may breed,

or the maintenance of any nuisance on the premises shall not be allowed.

§ 355.16 Control of flies, rats, mice, etc.

Flies, rats, mice, and other vermin shall be excluded from inspected plants and premises.

§ 355.17 Tagging equipment "U.S. rejected."

When necessary, inspectors shall attach a ''U.S. rejected'' tag to any equipment or utensil which is unclean or the use of which would be in conflict with the provisions of this part. No equipment or utensil so tagged shall again be used until made acceptable under this part and until removal of the tag. Such tag shall not be removed from the equipment or utensil by anyone other than an inspector.

§ 355.18 Drawings and specifications to be furnished.

Triplicate copies of complete drawings and specifications for remodeling inspected plants or for new structures at such plants shall be submitted to the Administrator and approval obtained for the plans in advance of construction.

INSPECTION PROCEDURE

§ 355.19 Inspector to be informed when plant operates.

The management of an inspected plant shall inform the inspector or the circuit supervisor when work in each department has been concluded for the day, and the day and hour when work will be resumed therein. There shall be no preparation of certified products at an inspected plant except under the supervision of an inspector.

§ 355.20 Inspector to have access to plant at all times.

For the purpose of examination or inspection necessary to enforce any of the provisions of this part, inspectors shall have access at all times by day or night, whether the plant is being operated or not, to every part of an inspected plant.

§ 355.21 Products entering inspected plants.

All products of a kind certified under this part or materials to be used in the preparation of such products when brought into an inspected plant shall be identified and inspected at the time of receipt and be subject to further inspection in such manner and at such time as may be deemed necessary. If, upon inspection, any such article is found to be unsound or otherwise unfit, it shall be handled as provided in § 355.28.

§ 355.22 Designation of place of receipt of returned products.

Certified products returned to an inspected plant shall be received at a dock or place specifically designated for the purpose by the plant management with the approval of the circuit supervisor. Such returned products shall be inspected there by the inspector before further entering the plant.

§ 355.23 Tagging products "U.S. retained."

A ''U.S. Retained'' tag shall be placed by an inspector at the time of inspection on all certified products, materials to be used in the preparation of certified products, or containers thereof, whenever such certified products, materials, or containers are suspected of being unsound or otherwise unfit or not in conformity with the requirements contained in this part. Such tags so placed shall not be removed by anyone other than an inspector.

§ 355.24 Processes to be supervised.

All processes used in the preparation of the certified products shall be supervised by an inspector. All steps in the process of manufacture shall be conducted carefully and with strict cleanliness. Inspected plants shall not prepare products of a kind certified under this part unless they conform with the regulations contained in this part.

§ 355.25 Canning with heat processing and hermetically sealed containers; closures; code marking; heat processing; incubation.

(a) Containers shall be cleaned thoroughly immediately before filling, and

precaution must be taken to avoid soiling the inner surfaces subsequently.

(b) The inside surfaces of containers of metal, glass, or other material shall be washed by spraying in an inverted position with running water at a temperature of at least 180 °F. The container washing equipment shall be provided with a thermometer to register the temperature of the water used for cleaning the containers.

(c) Perfect closure is required for hermetically sealed containers. Heat processing shall follow promptly after closing.

(d) Careful inspection shall be made of the containers by competent plant employees immediately after closing, and containers which are defectively filled or defectively closed, or which show inadequate vacuum, shall not be further processed until the defect has been corrected. The containers shall again be inspected by plant employees when they have cooled sufficiently for handling after processing by heating. The contents of defective containers shall be condemned unless correction of the defect is accomplished within six hours following the sealing of the containers or completion of the heat processing, as the case may be, except that (1) if the defective condition is discovered during an afternoon run the cans of product may be held in coolers at a temperature not exceeding 38 °F. under conditions that will promptly and effectively chill them until the following day when the defect may be corrected; and (2) short vacuum or overstuffed cans of products which have not been handled in accordance with the above may be incubated as provided in paragraph (i) of this section in the inspected plant under Program supervision, after which the cans shall be opened and the sound products passed.

(e) Canned products shall not be passed unless, after cooling to atmospheric temperature, they show the external characteristic of sound cans; that is, the cans shall not be overfilled, the ends of the cans shall be concave, there shall be no bulging of the cans, the sides and ends of the cans shall conform to the products, and there shall be no slack or loose tin in the cans.

(f) All canned products shall be plainly and permanently marked on the containers by code or otherwise with the identity of the contents and date of canning. The code used and its meaning shall be on record in the office of the circuit supervisor before use.

(g) The canned products must be processed at such temperature and for such period of time as will assure keeping without refrigeration under usual conditions of storage and transportation as evidenced by the incubation test.

(h) Lots of canned products shall be identified during their handling preparatory to and during heat processing by tagging the baskets or cages in which the cans are being conveyed, with a tag which will change color on going through the heat processing or by other effective means so as to insure the proper channeling of the products for effective heat processing after closing the cans.

(i) Facilities shall be provided to incubate at least representative samples of the fully processed canned products. The incubation shall consist of holding the canned products for at least 10 days at about 98 °F. The extent to which incubation tests shall be required by inspectors depends on conditions such as the record of the inspected plant in conducting canning operations, the extent to which the plant furnishes competent supervision and inspection in connection with the canning operations, the character of the equipment used, and the degree to which such equipment is maintained at maximum efficiency. Such factors shall be considered by the circuit supervisor in determining the extent of incubation testing at a particular plant. In the event of failure by an inspected plant to provide suitable facilities for incubation of test samples, the circuit supervisor may require holding of the entire lot under such conditions and for such period of time as may, in his discretion, be necessary to establish the stability of the canned products. The circuit supervisor may permit lots of canned certified products to be shipped from the inspected plant prior to completion of sample incubation when he has no reason to suspect unsoundness in the particular lots, and under circumstances

which will assure the return of the products to the plant for inspection should such action be indicated by the incubation results.

§ 355.26 Samples of certified products, ingredients, etc., to be taken for examination.

Samples of certified products, water, chemicals, flavorings or other articles in an inspected plant shall be taken without cost to the Program for an examination as often as may be deemed necessary for the efficient conduct of the inspection. The frequency of sampling shall be determined by the needs of the inspection.

§ 355.27 Reports of violations of regulations.

Inspectors shall report to the circuit supervisor violations of or failures to conform with these regulations which occur at inspected plants, and the circuit supervisor shall report the same to the Administrator.

DISPOSAL OF CONDEMNED MATERIAL

§ 355.28 Unfit material to be condemned.

Subject to § 355.41, any certified products, or ingredients intended for use therein, which are decomposed or adulterated or otherwise unsound or unfit for use shall be condemned and destroyed, except that if the adulteration is such as will not preclude their legitimate use for some purpose other than the preparation of the certified products, they may be released by authorized inspectors for such other purpose for disposition under the supervision of the proper local, State, or Federal official. The operator of the inspected plant shall make such arrangement as may be necessary with the proper officials for the disposition of the article.

COMPOSITION OF CERTIFIED PRODUCTS

§ 355.29 Composition of certified products for dogs, cats, and other carnivora.

(a) *Composition of canned or semi-moist certified maintenance food.* (1) Only ingredients which are normal to canned or semi-moist food for dogs, cats, and other carnivora, which are favorable to adequate nutrition, and which are classed by the Administrator as conforming with requirements contained in this part shall be used in the preparation of certified maintenance food.

(2) Not less than 30 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products, shall be used in the preparation of canned or semimoist certified maintenance food. Upon specific approval of the Administrator, combinations of the above specified ingredients may be used. The uncooked weight of the meat or animal food meat byproduct or both, or of the horse meat or animal food horse meat byproduct or both, or of the mule meat or animal food mule meat byproduct or both, or of the poultry products, or of the combinations thereof, shall be used in the calculation, and the percentage shall be obtained by relating this weight to the total weight of the certified maintenance food.

(3) Certified maintenance food shall contain not less than 10 percent of protein.

(4) Certified maintenance food shall contain a level of minerals and vitamins generally recognized to be essential to the nutritional value of the food.

(5) Vegetables and grains and their derivatives, used as ingredients of certified maintenance food, shall be of good quality, shall be free from discoloration, mold, smut, and insect infestation, and shall be otherwise fit for use as animal food.

(6) Inedible material such as tankage, dried blood, bone meal, and the like shall not be used as ingredients of certified maintenance food.

(7) Semi-moist certified maintenance food shall have a soft granular consistency, shall be shelf stable, and shall be processed so that the moisture content thereof does not exceed 27 percent of the net weight of such food.

(b) *Composition of canned or fresh frozen certified supplemental animal foods.* (1) Certified animal protein supplement shall comply with the following requirements:

(i) Certified animal protein supplement shall contain not less than 95 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products. Upon specific approval of the Administrator, combinations of the above specified ingredients may be used;

(ii) Certified animal protein supplement shall have added thereto a sufficient amount of fresh ground bone or other acceptable agent to satisfy the requirements of the regulations promulgated under the Meat Inspection Act (34 Stat. 1260), as amended (21 U.S.C. 71 *et seq.*), and the Horse Meat Act (41 Stat. 241; 21 U.S.C. 96), in order to insure decharacterization of the product for human food purposes;

(iii) Certified animal protein supplement may contain not more than 3 percent wheat flour or other processing aid acceptable to the Administrator, which shall be of good quality, shall be free from insect infestation, and shall be otherwise fit for use as animal food;

(iv) Certified animal protein supplement shall contain not less than 15 percent protein; and

(v) Certified animal protein supplement shall contain not less than 3 percent fat.

(2) Certified pet food supplement shall comply with the following requirements:

(i) Certified pet food supplement shall contain not less than 50 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products. Upon specific approval of the Administrator, combinations of the above specified ingredients may be used;

(ii) Certified pet food supplement shall have added thereto a sufficient amount of fresh ground bone or other acceptable agent to satisfy the requirements of the regulations promulgated under the Meat Inspection Act (34 Stat. 1260), as amended (21 U.S.C. 71 *et seq.*), and the Horse Meat Act (41 Stat. 241; 21 U.S.C. 96), in order to insure decharacterization of the product for human food purposes;

(iii) Certified pet food supplement may contain various cereals, flours, vegetables, flavorings, seasonings and other processing aids acceptable to the Administrator which shall be of good quality, shall be free from discoloration, mold, smut, and insect infestation, and shall be otherwise fit for use as animal food;

(iv) Certified pet food supplement shall contain not less than 11 percent protein;

(v) Certified pet food supplement shall contain not less than 3 percent fat; and

(vi) Certified pet food supplement may not contain more than 74 percent moisture.

(c) *Composition of canned certified variety pet food.* (1) Certified variety pet food shall contain not less than 25 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products. Upon specific approval of the Administrator, combinations of the above specified ingredients may be used.

(2) Certified variety pet food shall contain a variety of vegetables and may contain other ingredients which are favorable to adequate nutrition.

(3) Vegetables and grains and their derivatives used as ingredients of certified variety pet food shall be of good quality, shall be free from discoloration, mold, smut, and insect infestation, and shall be otherwise fit for use as animal food.

(4) Certified variety pet food shall contain not less than 8 percent protein.

(5) Certified variety pet food shall contain not less than 2 percent fat.

(6) Certified variety pet food may contain not more than 75 percent moisture.

(d) Certified products for dogs, cats, and other carnivora may contain whale meat, fish, and animal food poultry byproducts or combinations thereof as optional ingredients in lieu of some but not all of the ingredients named in paragraphs (a)(2), (b)(1)(i), and (c)(1) of

this section, respectively, upon specific approval of the Administrator.

[26 FR 3984, May 9, 1961, as amended at 29 FR 9819, July 22, 1964; 29 FR 18419, Dec. 25, 1964. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 30 FR 10284, Aug. 19, 1965; 32 FR 13115, Sept. 15, 1967; 33 FR 6707, May 2, 1968]

SUPERVISION

§ 355.31 Supervision by inspector.

No container which bears or is to bear a label as provided for under this part shall be filled in whole or in part except with certified products which have been inspected in compliance with this part, which are sound, healthful, wholesome, and otherwise fit for dogs, cats, and other carnivora, and which are strictly in accordance with the statements on the label. No such container shall be filled in whole or in part and no such label shall be affixed thereto except under the supervision of an inspector.

LABELING

§ 355.32 Labeling required.

Each container of inspected and certified product shall have affixed thereto a label bearing the following information, prominently displayed:

(a) The name of the product, class of product, ingredient statement, and the animal foods inspection legend in the manner provided by paragraphs (a) (1), (2), (3), (4), (5), and (6) of this section.

(1) The name of the canned or semimoist certified food shall include words such as ''dog food,'' ''cat food,'' ''dog and cat food,'' or ''fox food,'' accompanied with such references to optional ingredients as may be required by the Administrator under this part. Product names shall not be misleading in regard to class of canned or semimoist certified food for which label is intended.

(2) Class of product as outlined in paragraphs (a), (b), and (c) of § 355.29 shall be declared on either the main display or 20 percent panel of the label.

(3) The word ''ingredients,'' followed by a complete list of ingredients of the food in the order of their predominance and by their common or usual names, shall appear on the label with the name of the food.

(4) The inspection legend for canned, semi-moist or frozen certified animal food shall appear on the label in the form shown herewith, except that the plant number need not appear with the legend when such number is embossed on the sealed metal container as provided in § 355.33.

(5) When a product is prepared in whole from any of the items defined in § 355.2 (i) through (n), its name shall identify the item and there shall appear contiguous to the name of the item the name of the decharacterizing agent used, followed by the word ''added'' as, for example, ''bone added.''

(6) When wheat flour or other processing aid is added to the product, there shall appear on the label, with the name of the decharacterizing agent, in predominating order, the name of the processing aid, as, for example, ''Wheat flour and bone added'' or ''Bone and wheat flour added.''

(b) A statement of the quantity of contents of the container, representing in terms of avoirdupois weight the quantity of product in the container.

(c) The name and place of business of the manufacturer, packer, or distributor. The name under which inspection is granted to a plant may appear without qualification on the label of a product prepared by that plant. When the certified product is not prepared by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with the product as, for example, ''Prepared for _____.''

[23 FR 10107, Dec. 23, 1958, as amended at 25 FR 1357, Feb. 16, 1960; 26 FR 3984, May 9, 1961; 29 FR 9819, July 22, 1964. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 32 FR 13115, Sept. 15, 1967]

§ 355.33 Plant number to be embossed on metal containers.

The official number assigned to an inspected plant under § 355.8 shall be embossed on all sealed metal containers of certified products filled in such plant, except that such containers which bear labels lithographed directly on the container and in which the plant number is incorporated need not have the plant number embossed thereon. Labels and embossed code identification shall be affixed so as not to obscure the embossed plant number.

[23 FR 10107, Dec. 23, 1958. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 13115, Sept. 15, 1967; 38 FR 29215, Oct. 23, 1973]

§ 355.34 Labels, approval of, by Administrator.

(a) Except as provided in paragraph (c) of this section, no label shall be used on any container of certified products until it has been approved by the Administrator. For the convenience of the inspected plant, sketches or proofs of proposed labels may be submitted in triplicate to the Administrator for approval, and the preparation of the finished labels deferred until such approval is obtained. All finished labels shall be submitted in quadruplicate to the Administrator for approval. In the case of lithographed labels, paper take-offs in lieu of sections of the metal containers shall be submitted for approval. Such paper take-offs shall not be in the form of a negative but shall be a complete reproduction of the label as it will appear on the package, including any color scheme involved.

(b) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter for use on, or to be placed within, containers and coverings of certified products shall be submitted for approval in the same manner as provided for labels in paragraph (a) of this section, except that inspectors in charge may permit the use of such devices if they contain no reference to the certified products and bear no misleading feature.

(c) Stencils, labels, box dies, and brands may be used on shipping containers, including tierces, barrels, drums, boxes, crates, and large-size fiberboard containers, without approval by the Administrator, provided the markings are applicable to the certified products, are not false or deceptive, and are used with the approval of the circuit supervisor.

(d) No certified product and no container thereof shall be labeled with any false or deceptive term, and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of the origin, quality, or quantity of the product shall appear on any label.

§ 355.35 Label information to be displayed on principal panel.

The label information required by § 355.32 shall be displayed on the principal panel or panels of the label except that label information other than the name of the product and the ingredient statement may be displayed on a panel immediately adjacent to the principal panel or panels if such supplemental panel consists of at least 20 percent of the label and is reserved exclusively for required labeling information.

§ 355.36 Obsolete labels.

At least once each year, each inspected plant shall submit to the Administrator, in quadruplicate, a list of approvals for labels that have become obsolete, accompanied by a statement that such approvals are no longer desired. The approvals shall be identified by the number, the date of approval, and the name of the product.

§ 355.37 Alteration or limitation of statement of certification.

The statement of certification provided for by § 355.32(a)(4) shall not be altered, defaced, imitated, or simulated in any respect or used for the purpose of misrepresentation or deception.

[25 FR 1357, Feb. 16, 1960. Redesignated at 30 FR 4195, Mar. 31, 1965]

PENALTIES

§ 355.38 Withdrawal of service.

After opportunity for hearing before a proper official of the Department has been accorded the operator of an inspected plant, the inspection, certification, and identification provided for in this part may be withdrawn from

such plant if the operator: (a) Persistently fails to comply with any provision of the regulations in this part or of instructions or directions issued thereunder; (b) makes any willful misrepresentation or engages in any fraudulent or deceptive practice in connection with the making of any application for service; (c) violates § 355.37; or (d) interferes with or obstructs any program employee in the performance of his duties under the regulations in this part by intimidation, threats, or other improper means. Pending final determination of the matter, the Administrator may suspend such inspection, certification, and identification without hearing in cases of willfulness or those in which the public health, interest, or safety requires such action. The operator of the inspected plant shall be notified of the Administrator's decision to suspend such inspection, certification or identification service, and the reasons therefor, in writing, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to suspend such inspection, certification or identification service shall be effective upon such oral or written notification, whichever is earlier, to the operator of the plant. If such notification is oral, the Administrator shall confirm such decision and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator of the inspected plant, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)). In other cases, prior to the institution of proceedings for any withdrawal or suspension, the facts or conduct which may warrant such action shall be called to the attention of the operator in writing and he shall be given an opportunity to demonstrate or achieve compliance with the requirements of the regulations in this part and instructions and directions issued thereunder.

[23 FR 10107, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 43 FR 11148, Mar. 17, 1978]

APPEALS

§ 355.39 Appeals from decisions made under this part.

Any appeal from a decision by an employee of the Program shall be made to his immediate superior having jurisdiction over the subject matter of the appeal.

REPORTS

§ 355.40 Plants to furnish information for reports.

Each day the operator of every inspected plant shall furnish the inspector assigned to that plant with a statement of the number of pounds of product certified by the inspector.

(Approved by the Office of Management and Budget under control number 0583–0036)

[23 FR 10107, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 47 FR 746, Jan. 7, 1982]

MULE MEAT AND ANIMAL FOOD, MULE MEAT BY-PRODUCT

§ 355.41 Antemortem and postmortem inspection for mules.

(a)(1) An antemortem examination and inspection shall be made of all mules about to be slaughtered for use in the preparation of products under this part, before their slaughter shall be allowed for such use. Such inspection shall be made on the day of slaughter.

(2) Mules found on such inspection to show symptoms of disease shall be set apart and slaughtered separately. Those found to be affected with strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), infectious anemia (swamp fever), dourine, acute influenza, generalized osteoporosis, glanders, farcy, or other malignant disorder, acute inflammatory lameness or extensive fistula, shall be condemned and destroyed. Any mule which is suspected on antemortem inspection of being infected with glanders shall be tested with mallein, and any mule which on physical examination is suspected of being affected with dourine shall be held for further examination or for

such test as the Administrator may prescribe.

(b)(1) A careful postmortem examination and inspection shall be made of all carcasses and parts thereof of all mules inspected under this section, at the time of slaughter. All carcasses and parts of mules found to be affected with any disease listed under paragraph (a) of this section shall be condemned and destroyed.

(2) Other carcasses and parts of mules found abnormal or diseased upon inspection under this section shall be disposed of in accordance with such provisions of the Meat Inspection Regulations (subchapter A of this chapter) as are deemed applicable by the Administrator.

§ 355.42 Marking of mule meat and animal food mule meat by-product.

All mule meat and animal food mule meat by-product inspected under this part shall be marked and identified as the Administrator may require in any particular case.

[25 FR 1357, Feb. 16, 1960. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 32 FR 13115, Sept. 15, 1967]

§ 355.43 Scope and applicability of rules of practice.

The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, admininstrative proceedings under the regulations in this part (9 CFR part 355).

[43 FR 11148, Mar. 17, 1978]

PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS

Sec.

AUTHORITY: 7 U.S.C. 1622; 7 CFR 2.18 (g) and (i) and 2.53.

SOURCE: 41 FR 23715, June 11, 1976, unless otherwise noted.

§ 362.1 Definitions.

The definitions in § 381.1 are incorporated in this part except for the definitions excluded in § 362.2(a). In addition to those definitions, the following definitions will be applicable to the regulations in this part.

(a) *Act.* ''Act'' means the Agricultural Marketing Act of 1946, as amended (60 Stat. 1087, as amended; 7 U.S.C. 1621 *et seq.*).

(b) *Inspector.* ''Inspector'' means any officer or employee of the Department authorized to perform any duties under the regulations in this part.

(c) *Person.* ''Person'' means any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other organized business unit.

(d) *Poultry.* ''Poultry'' means any migratory water fowl or game bird, whether dead or alive.

(e) *Poultry Product.* ''Poultry product'' means any poultry carcass or part thereof; or any human food product which is made wholly or in part from the carcass of any domesticated bird (as defined in § 381.1(b) of this chapter) and is excepted from the inspection requirements of the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*).

[66 FR 22905, May 7, 2001]

§ 362.2 Types and availability of service.

Upon application, in accordance with § 362.3, the following types of service may be furnished under the regulations in this part:

(a) *Inspection service.* An inspection and certification service for wholesomeness relating to the slaughter and processing of poultry and the processing of poultry products. All provisions of Part 381 and §§ 416.1 through 416.6 of this chapter shall apply to the slaughter of poultry, and the preparation, labeling, and certification of the poultry and poultry products processed under this poultry inspection service except for the following provisions: the definitions of ''Act,'' ''animal food manufacturer,'' ''Inspection Service,'' ''inspector,'' ''Inspector in Charge,'' ''poultry,'' ''poultry product,'' ''poultry food product,'' ''poultry products broker,'' ''renderer,'' and ''U.S. Refused

Entry'' in §§ 381.1 (b), 381.3 (a), 381.6, 381.10, 381.13–381.17, 381.21, 381.29, 381.39–381.42, 381.175 (a)(2), 381.175 (a)(3), 381.179, 381.185–381.187, 381.192, and 381.195–381.225.

(b) *Export certification service.* At the request of any person intending to export any slaughtered poultry or poultry product, inspectors may make certification regarding products for human food purposes, to be exported, as meeting conditions or standards that are not imposed or are in addition to those imposed by the regulations in this chapter and the laws under which such regulations were issued.

(c) *Identification Service.* (1) Poultry or other product that is federally inspected and passed at an official establishment, or upon importation, under the Poultry Products Inspection Act, is officially marked to identify it as federally inspected and passed. In order to facilitate the division of such poultry or other product into smaller portions or its combination into larger units and still maintain its identify as product which has been federally inspected and passed and so marked, inspectors may supervise the handling and weighing of the product and mark such portions and units with the official mark of inspection when they determine that identify has been maintained.

(2) At the time service is furnished, product must be sound, wholesome, and fit for human food. The service will be available only on premises other than those of an official establishment. The sanitation of the place or area where service is furnished must comply with provisions of §§ 416.1 through 416.6 of this chapter.

(3) The mark of inspection shall be applied only under the immediate supervision of an inspector.

(4) This service does not cover further cutting and processing of products. These activities must take place at an official establishment.

(5) The registration and recordkeeping requirements enumerated in Part 381, subpart Q, of this chapter shall apply to persons requesting voluntary identification service under this paragraph (c).

[66 FR 22905, May 7, 2001]

§ 362.3 Application for service.

Any person who desires to receive service under the regulations in this part for poultry or other product eligible therefor under such regulations may make application for service to the Administrator, upon an application form which will be furnished by the Administrator upon request to the Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. The application must include all the information called for by that form. In case of change of name, ownership, management, or location, a new application shall be made.

(Approved by the Office of Management and Budget under control number 0583–0036)

[41 FR 23715, June 11, 1976, as amended at 47 FR 746, Jan. 7, 1982]

§ 362.4 Denial or withdrawal of service.

(a) *For disciplinary reasons*—(1) *Bases for denial or withdrawal.* An application or request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person who, or whose employee or agent in the scope of his employment or agency, (i) has willfully made any misrepresentation or has committed any other fraudulent or deceptive practice in connection with any application or request for service under the regulations in this chapter; (ii) has given or attempted to give, as a loan or for any other purpose, any money, favor, or other thing of value, to any employee of the Department authorized to perform any function under the regulations in this chapter; (iii) has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee of the Department in the performance of his duties under the regulations in this chapter by intimidation, threats, assaults, abuse, or any other improper means; (iv) has knowingly falsely made, issued, altered, forged, or counterfeited any official certificate, memorandum, mark, or other identification, or device for making any such mark or identification authorized or issued under this chapter; (v) has knowingly uttered, published, or used as true any such

falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark, identification, or device; (vi) has knowingly obtained or retained possession of any such falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark, identification, or device, or of any carcass or poultry or product bearing any such falsely made, issued, altered, forged or counterfeited certificate, memorandum, mark, or identification; (vii) has knowingly represented that any carcass, poultry, or product has been officially inspected and passed (by an authorized inspector) under this chapter, when it had not in fact been so inspected; (viii) has, within the previous ten years, been convicted of any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food, or fraud in connection with transactions in food, or any felony indicating a lack of the integrity needed for the conduct of operations affecting the public health; (ix) has in any manner not specified in this paragraph violated subsection 203(h) of the Act:

Provided, That paragraph (a)(1)(vi) of this section shall not be deemed to be violated if the person in possession of any item mentioned therein notifies the inspector without delay that he has possession of such item and, in the case of an official device, surrenders it to the inspector, and, in the case of any other item, surrenders it to the inspector or destroys it or brings it into compliance with the regulations by obliterating or removing the violative features under supervision of the inspector; *And provided further,* That an application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from any person who operates an establishment for which he has made application for service if, with the knowledge of such operator, any other person conducting any operations in such establishment has committed any of the offenses specified in paragraphs (a)(1) (i) through (ix) of this section after such application was made. Moreover, an application or a request for service made in the name of a person otherwise eligible for service under the regulations may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, such a person (a) in case the service is or would be performed at an establishment operated (1) by a corporation, partnership, or other person from whom the benefits of the service are currently being withheld under this chapter, or (2) by a corporation, partnership, or other person having an officer, director, partner, or substantial investor from whom the benefits of service under this chapter are currently being withheld and who has any authority with respect to the establishment where service is or would be performed, or (b) in case the service is or would be performed with respect to any poultry or product in which any corporation, partnership, or other person within (a)(1) of this section has a contract or other financial interest.

(2) *Procedure.* An application or request for service may be rejected, or benefits of the service may be otherwise denied to or withdrawn by the Secretary, as provided by this paragraph, after notice and opportunity for hearing before a proper official of the Department. The Administrator may reject an application or request for service or deny or withdraw service under this paragraph without hearing, pending final determination of the matter, when he determines that the public interest so requires. The operator or applicant of such plant shall be notified of the Administrator's decision to reject the application or request for service or to deny or withdraw such service, and the reasons therefor, in writing, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to reject an application or request for service or to deny or withdraw the benefits of service under the Act shall be effective upon such oral or written notification, whichever is earlier, to the operator or applicant of such plant. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in

the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(b) *For correctable cause*—(1) *Basis for denial or withdrawal.* An application or request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person whose establishment does not meet the requirements as to premises, facilities, and equipment, and the operation thereof, prescribed in the regulations to prevent the distribution of adulterated poultry or poultry products, or who has not received approval of labeling and containers to be used at the establishment as required by the regulations.

(2) *Procedure.* An application or request for service may be rejected, or benefits of the service may be otherwise denied to or withdrawn by the Secretary, as provided by this paragraph, after notice and opportunity for hearing before a proper official of the Department. The Administrator may reject an application or request for service or deny or withdraw service under this paragraph without hearing, pending final determination of the matter, when he determines that the public interest so requires. The operator or applicant of such plant shall be notified of the Administrator's decision to reject the application or request for service or to deny or withdraw such service, and the reasons therefor, in writing, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to reject an application or request for service or to deny or withdraw the benefits of service under the Act shall be effective upon such oral or written notification, whichever is earlier, to the operator or applicant of such plant. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(c) *For miscellaneous reasons.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person, without a hearing, by the official in charge of the appropriate regional office, with the concurrence of the Regional Director (1) for administrative reasons such as the nonavailability of personnel to perform the service; (2) for the failure to pay for service; (3) in case the application or request relates to birds or products which are not eligible for service under this part 362; or (4) in case the person is a partnership, corporation, or other person from whom the benefits of the service are currently being withheld under paragraph (a) of this section. Notice of such rejection, denial, or withdrawal, and the reasons therefor, shall promptly be given to the person involved. The operator or applicant of such plant shall be notified of such decisions to reject an application or request for service or to deny or withdraw the benefits of the service, and the reasons therefor, in writing, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. Such decision shall be effective upon such oral or written notification, whichever is earlier, to the operator or applicant of such plant. If such notification is oral, the person making such decision shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(d) *Scope and applicability of rules of practice.* The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 362).

[41 FR 23715, June 11, 1976, as amended at 43 FR 11148, Mar. 17, 1978]

§ 362.5 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in accordance with this section, and, if required by the Administrator, the fees and charges shall be paid in advance.

(b) The fees and charges provided for in this section shall be paid by check,

draft, or money order payable to the Treasurer of the United States and shall be remitted promptly to the Administrator upon furnishing to the applicant a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rates specified in §§391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall cover the costs of the services and shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover the cost of travel and other expenses incurred by the Service in connection with the furnishing of the service.

(e) Exporters that submit electronic export certificate applications will be charged a fee per application submitted.

(f) For each calendar year, FSIS will calculate the electronic export certificate application fee, using the following formula: Labor Costs (Technical Support Cost + Export Library Maintenance Cost) + Information Technology Costs (On-going operations Cost + Maintenance Cost + eAuthentication Cost), divided by the number of export applications.

(g) FSIS will publish notice of the electronic export certificate application fee annually in the FEDERAL REGISTER.

[41 FR 23715, June 11, 1976, as amended at 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989; 81 FR 42234, June 29, 2016]

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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Subpart X [Reserved]

Subpart Y—Nutrition Labeling

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 451–472; 7 CFR 2.18, 2.53.

SOURCE: 37 FR 9706, May 16, 1972, unless otherwise noted.

Subpart A—Definitions

§ 381.1 Definitions.

(a) For the purposes of the regulations in this part, unless otherwise required by the context, the singular form shall also import the plural and the masculine form shall also import the feminine, and vice versa.

(b) For the purposes of such regulations, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

Acceptable. ''Acceptable'' means suitable for the purpose intended and acceptable to the Administrator.

Act. ''Act'' means the Poultry Products Inspection Act (71 Stat. 441, as amended by the Wholesome Poultry Products Act, 82 Stat. 791; 21 U.S.C. 451 *et seq.*).

Adulterated. ''Adulterated'' applies to any poultry product under one or more of the following circumstances:

(i) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(ii)(*a*) If it bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or added deleterious substance (other than one which is a pesticide chemical in or on a raw agricultural commodity; a food additive; or a color additive) which may, in the judgment of the Administrator, make such article unfit for human food;

(*b*) If it is, in whole or part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(*c*) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(*d*) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act:

Provided, That an article which is not otherwise deemed adulterated under paragraphs (b)(4)(ii) (*b*), (*c*), or (*d*) of this section shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by the regulations in this part in official establishments;

(iii) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(iv) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(v) If it is, in whole or in part, the product of any poultry which has died otherwise than by slaughter;

(vi) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(vii) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a

regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act; or

(viii) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Animal food. Any article intended for use as food for dogs, cats, or other animals, derived wholly, or in part, from carcasses or parts or products of the carcass of poultry, except that the term animal food as used herein does not include (i) processed dry animal food or (ii) livestock or poultry feeds manufactured from processed poultry byproducts (such as poultry byproduct meal, hydrolyzed poultry feathers, and hydrolyzed poultry byproducts aggregate).

Animal food manufacturer. ''Animal Food Manufacturer'' means any person engaged in the business of manufacturing or processing animal food.

Applicant. ''Applicant'' means any person who requests inspection service, exemption, or other authorization under the regulations.

Biological residue. ''Biological Residue'' means any substance, including metabolites, remaining in poultry at the time of slaughter or in any of its tissues after slaughter, as the result of treatment or exposure of the live poultry to a pesticide, organic compound, metallic or other inorganic compound, hormone, hormone-like substance, growth promoter, antibiotic, anthelmintic, tranquilizer, or other agent that leaves a residue.

Capable of use as human food. The term ''capable of use as human food'' applies to any carcass, or part or product of a carcass of any poultry, unless it is denatured or otherwise identified as required by the regulations, or it is naturally inedible by humans.

Carcass. This term means all parts, including viscera, of any slaughtered poultry.

Commerce. ''Commerce'' means commerce between any State, any territory, or the District of Columbia, and any place outside thereof; or within any territory not organized with a legislative body, or the District of Columbia.

Consumer package. ''Consumer package'' means any container in which a poultry product is enclosed for the purpose of display and sale to household consumers.

Container. The term ''container'' includes any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

Edible. This term means that an article is intended for use as human food.

Egg Products Inspection Act. ''Egg Products Inspection Act'' means the Act so entitled, approved December 29, 1970 (84 Stat. 1620, 21 U.S.C. 1031 *et seq.*).

Federal Food, Drug, and Cosmetic Act. ''Federal Food, Drug, and Cosmetic Act'' means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and acts amendatory thereof or supplementary thereto (21 U.S.C. 301 *et seq.*).

Federal Meat Inspection Act. ''Federal Meat Inspection Act'' means the Act so entitled, approved March 4, 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act, 81 Stat. 584 (21 U.S.C. 601 *et seq.*).

Free from protruding pinfeathers. ''Free from protruding pinfeathers'' means that the carcass is free from protruding pinfeathers which are visible to an inspector during an examination of the carcass at normal operating speeds. However, a carcass may be considered as being free from protruding pinfeathers if it has a generally clean appearance (especially on the breast), and if not more than an occasional protruding pinfeather is in evidence during a more careful examination of the carcass.

Giblets. ''Giblets'' means the liver from which the bile sac has been removed, the heart from which the pericardial sac has been removed, and the gizzard from which the lining and contents have been removed: *Provided,* That each such organ has been properly trimmed and washed.

Immediate container. ''Immediate container'' includes any consumer package; or any other container in which

poultry products, not consumer packaged, are packed.

Inedible. This term means any carcass or any part of a carcass that is either naturally inedible by humans or is rendered unfit for human food by reason of adulteration or denaturing.

Inspected for wholesomeness. This term means that the poultry product so identified has been inspected and was found at the time of such inspection to be not adulterated.

Inspection. ''Inspection'' means any inspection required by the regulations to determine whether any poultry or poultry products comply with the requirements of the Act and the regulations.

Label. This term applies to any display of written, printed, or graphic matter upon any article or the immediate container (not including package liners) of any article.

Labeling. This term applies to all labels and other written, printed, or graphic matter (i) upon any article or any of its containers or wrappers, or (ii) accompanying such article.

Misbranded. This term applies to any poultry product under one or more of the following circumstances:

(i) If its labeling is false or misleading in any particular;

(ii) If it is offered for sale under the name of another food;

(iii) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(iv) If its container is so made, formed, or filled as to be misleading;

(v) If in a package or other container, unless it bears a label showing:

(*a*) The name and place of business of the manufacturer, packer, or distributor; and

(*b*) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in §381.121(a) with respect to the quantity of contents;

(vi) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(vii) If it purports to be or is represented as a food for which a definition and standard of identity or composition is prescribed by the regulations in subpart P of this part unless:

(*a*) It conforms to such definition and standard, and

(*b*) Its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(viii) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary,[2] and falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(ix) If it is not subject to the provisions of paragraph (b)(vii) of this section, unless its label bears:

(*a*) The common or usual name of the food, if any there be, and

(*b*) In case it is fabricated from two or more ingredients, the common or usual name of each ingredient, except as otherwise provided in §381.118(c);

(x) If it purports to be or is represented for special dietary uses, unless the label bears such information concerning its vitamin, mineral, and other dietary properties as is required by §381.124;

(xi) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided in §381.119, or

(xii) If it fails to bear, directly thereon or on its containers, when required by §381.123, the official inspection legend and the official establishment number of the establishment where the

[2] No such standards are currently in effect. However, §381.129 prohibits the use of false or misleading containers.

product was processed; and unrestricted by any of the foregoing; such other information as the Administrator may require in the regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compounds. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of poultry or poultry products, excluding labeling and packaging materials as covered in subpart N of this part.

Official certificate. This term means any certificate prescribed in subpart M of this part relating to poultry or poultry products.

Official device. This term means any label or other device prescribed in subpart M of this part for use in applying any official mark.

Official establishment. ''Official establishment'' means any establishment as determined by the Administrator at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained pursuant to the regulations.

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in this definition where inspections are authorized to be conducted as prescribed in § 381.199.

Official inspection legend. This term means the official inspection mark prescribed in § 381.96 or the official poultry identification mark prescribed in § 381.97, showing that an article was inspected for wholesomeness and passed in accordance with the Act.

Official mark. This term means any symbol prescribed in subpart M of this part to identify the status of any article or poultry under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for poultry products.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for the purposes of the Act and the regulations as under the Federal Food, Drug, and Cosmetic Act.

Poultry. ''Poultry'' means any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs, also termed young pigeons from one to about thirty days of age), whether live or dead.

Poultry product. (i) This term means any poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting those exempted from definition as a poultry product in § 381.15. Except where the context requires otherwise (e.g., in paragraph (b)(42) of this section), this term is limited to articles capable of use as human food.

(ii) *Poultry food product.* This term means any product capable of use as human food which is made in part from any poultry carcass or part thereof, excepting those exempted from definition as a poultry product in § 381.15.

Poultry products broker. ''Poultry products broker'' means any person engaged in the business of buying or selling poultry products on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person.

Process. Process used as a verb means to conduct any operation or combination of operations, whereby poultry is slaughtered, eviscerated, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed. The term ''process'' does not refer to freezing of poultry products, except when freezing is incidental to operations otherwise classed as ''processing'' under this paragraph.

Process authority. A person or organization with expert knowledge in poultry production process control and relevant regulations.

Process schedule. A written description of processing procedures, consisting of any number of specific, distinct, and ordered operations directly under control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production.

Ready-to-cook poultry. ''Ready-to-cook poultry'' means any slaughtered poultry free from protruding pinfeathers and vestigial feathers (hair or down), from which the head, feet, crop, oil gland, trachea, esophagus, entrails, and lungs have been removed, and from which the mature reproductive organs and kidneys may have been removed, and with or without the giblets, and which is suitable for cooking without need of further processing. Ready-to-cook poultry also means any cut-up or disjointed portion of poultry or other parts of poultry, such as reproductive organs, head, or feet that are suitable for cooking without need of further processing.

Regulations. ''Regulations'' means the provisions of this entire part.

Renderer. ''Renderer'' means any person engaged in the business of rendering carcasses, or parts or products of the carcasses, of poultry, except rendering conducted under inspection or exemption pursuant to the regulations.

Shipping container. ''Shipping container'' means any container used or intended for use in packaging the product packed in an immediate container.

Slaughter. ''Slaughter'' means the act of killing poultry for human food.

State. Except as otherwise provided in § 381.220 ''State'' means any State of the United States and the Commonwealth of Puerto Rico.

Supervision. This term means the controls, as prescribed in instructions to Inspection Service employees, to be exercised by them over particular operations to insure that such operations are conducted in compliance with the Act and the regulations in this part.

Territory. The term ''territory'' means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

United States. This term means the States, the District of Columbia, and the territories of the United States.

U.S. Condemned. This term means that the poultry carcass, or part or product of a poultry carcass, so identified was inspected and found to be adulterated and is condemned.

U.S. Detained. This term is applicable to poultry, poultry products, and other articles which are held in official custody in accordance with section 19 of the Act and § 381.210, pending disposal as provided in said section 19.

U.S. Refused Entry. This term means that the slaughtered poultry or other poultry product so identified was presented for inspection for entry into the United States and was found not to comply with the requirements of the Act.

U.S. Rejected. This term means that the equipment or facility so identified is prohibited from being used in the processing of any poultry or poultry product until such equipment or facility is found by an inspector to be sanitary and otherwise eligible for use under the regulations.

U.S. Retained. This term means that the poultry or carcass, or part or product of a carcass, of poultry so identified is held at an official establishment by the inspection service for further determination as to its disposal.

(c) For the purposes of the standard for cooked, smoked sausage (§ 319.180 of this chapter), the term ''poultry by-product'' means the skin, fat, gizzard, heart, or liver, or any combination thereof, of any poultry.

[37 FR 9706; May 16, 1972, as amended at 39 FR 4568, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 48 FR 6091, Feb. 10, 1983; 49 FR 2236, Jan. 19, 1984; 49 FR 3643, Jan. 30, 1984; 49 FR 47478, Dec. 5, 1984; 51 FR 37709, Oct. 24, 1986; 64 FR 745, Jan. 6, 1999; 64 FR 56416, Oct. 20, 1999; 66 FR 1770, Jan. 9, 2001; 66 FR 22905, May 7, 2001; 67 FR 13258, Mar. 22, 2002; 69 FR 255, Jan. 5, 2004; 79 FR 56233, Sept. 19, 2014]

Subpart B—Administration; Application of Inspection and Other Requirements

§ 381.3 Administration.

(a) [Reserved]

(b) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements: *Provided,* That such

waivers of the provisions of the regulations are not in conflict with the purposes or provisions of the Act.

(c) Pursuant to section 6 of the Act, the Administrator believes that, in establishments processing poultry products at which inspection under the Act and regulations is required, the frequency with which and the manner in which poultry products made from poultry previously slaughtered and eviscerated in official establishments are reinspected by Inspection Service employees should be based on considerations relevant to effective regulation of poultry products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, if so, to what extent the intensity of inspection coverage exceeds that which should be deemed necessary pursuant to section 6 of the Act, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Inspection Service employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(d) The determinations referred to in paragraph (c) of this section shall be made by the Inspection Service and shall reflect evaluations of the performance and the characteristics of such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person operating such establishment or by anyone responsibly connected with the business operating such establishment, as ''responsibly connected'' is defined in section 18(a) of the Act,

(ii) The competence of the person operating such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Inspection Service employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter and evisceration operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Federal Meat Inspection Act also are processed at such establishment, and

(vi) The size of such establishment.

(e)(1) For the period of experimentation described in paragraph (c) of this section, the frequency of inspection by Inspection Service employees of operations other than slaughter and evisceration may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (d)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (d)(2) of this section,[1]

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Inspection Service employees.

(ii) To the extent that frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this part, the Administrator will waive such provisions for the period of experimentation, in accordance with paragraph (b) of this section.

[37 FR 9706, May 16, 1972, as amended at 52 FR 10033, Mar. 30, 1987; 69 FR 255, Jan. 5, 2004]

§ 381.4 Inspection in accordance with methods prescribed or approved.

Inspection of poultry products shall be rendered pursuant to the regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

§ 381.5 Publications.

Publications under the Act and the regulations shall be made in the FEDERAL REGISTER and in such other media as the Administrator may designate.

§ 381.6 Establishments requiring inspection.

Inspection under the regulations is required at:

(a) Every establishment, except as provided in § 381.10 (a) and (b) or § 381.11, in which any poultry is slaughtered for transportation or sale in commerce, or in which any poultry products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food;

(b) Every establishment, except as provided in § 381.10 (a) and (b), (c), or (d), or § 381.11, within any State or organized territory which is designated in § 381.221 pursuant to section 5(c) of the Act, at which any poultry is slaughtered or any poultry products are processed, for use as human food solely for distribution within such jurisdiction; and

(c) Except as provided in § 381.10 (a) and (b), or (c), or § 381.11, every establishment designated by the Administrator pursuant to section 5(c) of the Act as one producing adulterated poultry products which would clearly endanger the public health.

§ 381.7 Coverage of all poultry and poultry products processed in official establishments.

All poultry and poultry products processed in an official establishment shall be inspected, handled, processed, marked, and labeled as required by the regulations.

Subpart C—Exemptions

§ 381.10 Exemptions for specified operations.

(a) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry products shall not apply to:

(1) Any retail dealer with respect to poultry products sold in commerce directly to consumers in an individual retail store, if the only processing operation performed by such retail dealer is the cutting up of poultry products on the premises where such sales to consumers are made: *Provided*, That such operation is conducted under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further*, That the poultry products sold in commerce are derived from poultry inspected and passed under the Act and such poultry

[1] These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

products are not adulterated or misbranded at the time of sale (except that the official inspection legend shall not be used). (For the purposes of this subparagraph, a retail dealer is any person who sells poultry products directly to consumers as defined in paragraph (d)(2)(vi) of this section and whose sales of poultry products to household consumers constitute, in terms of dollar value, at least 75 percent of his total sales of poultry products.)

(2) The slaughter of poultry, and the processing of poultry products, by any person in any territory not organized with a legislative body, solely for distribution within such territory: *Provided*, That such poultry is sound and healthy and is slaughtered under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further*, That the poultry products are not adulterated or misbranded when so distributed (except that the official inspection legend shall not be used).

(3) The slaughtering by any person of poultry of his own raising, and the processing by him and transportation in commerce of the poultry products exclusively for use by him and members of his household and his nonpaying guests and employees: *Provided*, That in lieu of complying with all the adulteration and misbranding provisions of the Act, such poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food, and the shipping containers of such poultry products bear the producer's name and address and the statement ''Exempted—P.L. 90–492.''

(4) The custom slaughter by any person of poultry delivered by the owner thereof for such slaughter, and the processing by such slaughterer and transportation in commerce of the poultry products exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and the employees: *Provided*, That such custom slaughterer does not engage in the business of buying or selling any poultry products capable of use as human food: *And provided further*, That in lieu of complying with all the adulteration and misbranding provisions of the Act, such poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean and fit for human food, and the shipping containers of such poultry products bear the owner's name and address and the statement ''Exempted—P.L. 90–492.''

(5) The slaughtering of sound and healthy poultry and processing of poultry products therefrom in any State or territory or the District of Columbia by any poultry producer on his own premises with respect to poultry raised on his premises, and the distribution by any person solely within such jurisdiction of the poultry products derived from such operations: *Provided*, That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when so distributed; (ii) such poultry products when so distributed, bear (in lieu of labeling that would otherwise be required) the producer's name and address and the statement ''Exempted—P.L. 90–492'' and such poultry products are not otherwise misbranded; (iii) such producer and distributor do not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (5) or (6) of this section; and (iv) neither such producer or distributor slaughters or processes the products of more poultry than allowed by paragraph (b) of this section.

(6) The slaughtering of sound and healthy poultry or the processing of poultry products of such poultry in any State or territory or the District of Columbia by any poultry producer or other person for distribution by him solely within such jurisdiction directly to household consumers, restaurants, hotels, and boardinghouses, for use in

their own dining rooms, or in the preparation of meals for sales direct to consumers: *Provided,* That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when distributed by such processor; (ii) such poultry products when so distributed bear (in lieu of labeling that would otherwise be required) the processor's name and address and the statement ''Exempted—P.L. 90–492'' and such poultry products are not otherwise misbranded; (iii) such processor does not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (6) or (5) of this section; and (iv) such processor does not exceed the volume limitation prescribed in paragraph (b) of this section.

(7) The operations and products of small enterprises (including poultry producers) not exempted under paragraphs (a) (1) through (6) of this section that are engaged in any State or territory or the District of Columbia in slaughtering and/or cutting up poultry for distribution as carcasses or parts thereof solely for distribution within such jurisdiction; *Provided,* That (i) such poultry is sound and healthy when slaughtered and is slaughtered and/or cut up and handled under such sanitary standards, practices and procedures as result in the preparation of poultry products that are not adulterated when so distributed; and (ii) when so distributed, such poultry products are not misbranded (except that the official inspection legend shall not be used).

(b) No person qualifies for any exemption specified in paragraph (a)(5), (6), or (7) of this section if, in the current calendar year, such person:

(1) Slaughters or processes the products of more than 20,000 poultry, or

(2) Slaughters or processes poultry products at a facility used for slaughtering or processing poultry products by any other person, except when the Administrator grants such exemption after determining, upon review of a person's application, that such an exemption will not impair effectuating the purposes of the Act.

(c) The provisions of the Act and the regulations do not apply to any poultry producer with respect to poultry, of his own raising on his own farm, which he slaughters if:

(1) Such producer slaughters not more than 1,000 poultry during the calendar year for which this exemption is being determined;

(2) Such poultry producer does not engage in buying or selling poultry products other than those produced from poultry raised on his own farm; and

(3) None of such poultry moves in ''commerce'' (as defined in § 381.1).

(d)(1) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar-retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For the purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants include any processing of poultry products except canning of poultry products and except slaughtering of poultry unless such slaughtering is conducted at a retail store with respect to live poultry purchased by the consumer at the retail store and processed by the retail store operator in accordance with the consumer's instructions.

(ii) A normal retail quantity is any quantity of a poultry product purchased by a household consumer from a retail supplier that in the aggregate does not exceed 75 pounds. A normal retail quantity sold by a retail supplier to other than a household consumer is any quantity that in the aggregate does not exceed 150 pounds.

(iii) A retail store is any place of business where:

(*a*) The sales of poultry products are made to consumers only;

(*b*) At least 75 percent, in terms of dollar value, of total sales of product

represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds $500. Notice of the adjusted dollar limitation will be published in the FEDERAL REGISTER.[1]

(*c*) Only federally or State inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

(*d*) No sale of poultry products is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(*e*) The processing of poultry products for sale is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(iv) *Restaurants.* (*a*) A restaurant is any establishment where:

(*1*) Poultry products are processed only for sale or service in meals or as entrees directly to individual consumers at such establishments;

(*2*) Only federally inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

(*3*) No sale of poultry products is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(*4*) The processing of poultry products is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(*b*) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

(*c*) For purposes of this paragraph, operations conducted as a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares poultry products that are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirement of this paragraph: *Provided,* That the requirements of §§ 381.175 through 381.178 of this subchapter apply to such facility. *Provided further,* That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary if the Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its poultry products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator's determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) A similar retail-type establishment is any establishment which is a combination retail store and restaurant; any delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraph (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

[1] The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447–3219.

(vi) A consumer is any household consumer, hotel, or restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail establishment or restaurant claiming exemption under this paragraph (d) in any designated State or organized territory listed in §381.221 that is also identified in §381.224 as a jurisdiction that does not have or is not exercising adequate authority with respect to recordkeeping requirements, has been operated in violation of the conditions prescribed in this paragraph (d) for such exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail establishment or restaurant and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator determines that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail establishment or restaurant would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of his total monthly purchases and of his total monthly sales of poultry and poultry products. Such records shall separately show total sales to household consumers and total sales to other consumers, and shall be maintained for the period prescribed in §381.177. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(4) The adulteration and misbranding provisions of the Act and the regulations other than the requirement of the official inspection legend, apply to articles which are exempted from inspection under this paragraph (d).

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to poultry pizzas containing poultry product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the poultry pizzas are to be served in public or private nonprofit institutions, provided that the poultry pizzas are ready to eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1–102, except 1–102(z) and the provisions of Chapters 2 through 8, except sections 2–102 (a) and (b), 2–302(d), 2–403(a), 2–403(c), 2–404, 2–405, 2–407, 2–502 through 2–506, 2–508, 2–509, 4–105, 4–201(c), 4–208, 5–101(a), 5–103, 5–104, 5–202(c), 5–203, and 6–105, Part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78–2081, which is incorporated by reference, shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(3) Facilities and operations of businesses claiming this exemption shall

also conform to the following requirements:

(i) *Manual cleaning and sanitizing.* (A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

(*1*) Sinks shall be cleaned prior to use.

(*2*) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(*3*) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(*4*) Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(i)(E) (*1*) through (*4*) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

(*1*) Immersion for at least ½ minute in clean, hot water at a temperature of at least 170 °F; or

(*2*) Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or

(*3*) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or

(*4*) Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or

(*5*) Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(*6*) Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(i)(E)(*4*) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

(*1*) An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and

(*2*) A numerically scaled indicating thermometer, accurate to ±3 °F, convenient to the sink for frequent checks of water temperature; and

(*3*) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) *Mechanical cleaning and sanitizing.* (A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type

of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair. Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A ¼-inch IPS valve shall be provided immediately upstream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to ±3 °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or the use of easily movable dishtables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewashcycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: Provided, That,

(*1*) The temperature of the wash water shall not be less than 120 °F.

(*2*) The wash water shall be kept clean.

(*3*) Chemicals added for sanitization purposes shall be automatically dispensed.

(*4*) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(*5*) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(*6*) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(*7*) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(*1*) Single-tank, stationary-rack, dual-temperature machine:

Wash temperature	150 °F
Final rinse temperature	180 °F

(*2*) Single-tank, stationary-rack, single-temperature machine:

Wash temperature	165 °F
Final rinse temperature	165 °F

(*3*) Single-tank, conveyor machine:

Wash temperature	160 °F
Final rinse temperature	180 °F

(*4*) Multitank, conveyor machine:

Wash temperature	150 °F

Pumped rinse temperature .....160 °F
Final rinse temperature .....180 °F

(*5*) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):

Wash temperature .....140 °F
Final rinse temperature .....180 °F

(I) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) *Steam.* Steam used in contact with food or food-contact surfaces shall be free from any materials or additives other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term ''private nonprofit institution'' means ''a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.''

(5) The Administrator may withdraw or modify the exemption set forth in §381.10(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(6) The adulteration and misbranding provisions of the Act and the regulations apply to articles which are exempted from inspection under §381.10(e).

[37 FR 9706, May 16, 1972, as amended at 38 FR 16991, June 28, 1973; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 16, 1981; 48 FR 2959, Jan. 24, 1983; 51 FR 29909, Aug. 21, 1986; 53 FR 24679, June 30, 1988; 57 FR 34184, Aug. 3, 1992]

§ 381.11 Exemptions based on religious dietary laws.

(a) Any person who slaughters, processes, or otherwise handles poultry or poultry products which have been or are to be processed as required by recognized religious dietary laws may apply for exemption from specific provisions of the Act or regulations which are in conflict with such religious dietary laws. Any person desiring such an exemption shall apply in writing to the Meat and Poultry Inspection Program, Food Safety and Inspection Service,

Department of Agriculture, Washington, DC 20250, setting forth the specific provisions of the Act and the regulations from which exemption is sought and setting forth the provisions of the religious dietary laws in support of the requested exemption. In addition, the applicant for such an exemption shall submit a statement from the clerical official having jurisdiction over the enforcement of the religious dietary laws with respect to the poultry or poultry products involved, which identifies the requirements of such laws pertaining to the slaughter of the poultry and the processing or other handling of the poultry products involved, and certifies that such requirements are in conflict with specific provisions of the Act and regulations from which the exemption is sought.

(b) The Administrator, upon a determination that an exemption should be granted, will grant such exemption to the extent necessary to avoid conflict with the religious requirements while still effectuating the purposes of the Act. He may impose such conditions as to sanitary standards, practices, and procedures in granting such exemption as he deems necessary to effectuate the purposes of the Act. Any person who processes poultry or poultry products under exemption from certain requirements as provided in this section shall be subject to all of the other applicable provisions of the Act and the regulations. Processing plants shall meet the sanitary requirements set forth in this part and unless exempted from inspection under the provisions of this subpart, shall be required to qualify for inspection and operate as official establishments. Slaughtered poultry which is prepared under an exemption authorizing the sale of noneviscerated poultry in commerce shall be individually identified with a label approved by the Administrator which identifies the clerical official under whose supervision the poultry was slaughtered.

§ 381.12 Effect of religious dietary laws exemptions on other persons.

Whenever a slaughterer or processor is granted an exemption under § 381.11 with respect to the slaughtering or processing of any poultry or poultry products under this part, under specified conditions, the sale, offer for sale, transportation and other handling in commerce by any person of such poultry and poultry products in accordance with such conditions is hereby authorized, except as restricted by the Act.

§ 381.13 Suspension or termination of exemptions.

(a) The Administrator may, by order, in accordance with the applicable rules of practice suspend or terminate any exemption under § 381.10(a) with respect to any person whenever he finds that such action will aid in effectuating the purposes of the Act. Failure to comply with the conditions of the exemption, including, but not limited to, failure to process poultry and poultry products under clean and sanitary conditions may result in termination of an exemption, in addition to any other penalties provided by law.

(b) Except as provided in § 381.10(c), the Administrator may extend the requirements of the Act to any establishment in any State or organized territory at which poultry products are processed for distribution solely within such jurisdiction if he determines in accordance with the provisions of subparagraph 5(c)(1) of the Act that the establishment is producing adulterated poultry products which would clearly endanger the public health.

§ 381.14 Inspection concerning purportedly exempted operations.

Inspectors of the Inspection Service are authorized to make inspections in accordance with law to ascertain whether any of the provisions of the Act or the regulations applying to producers, retailers, or other persons purporting to be exempted from any requirements under this subpart have been violated.

§ 381.15 Exemption from definition of "poultry product" of certain human food products containing poultry.

The following articles contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry. Therefore said articles are exempted from the definition of ''poultry product'' and the requirements of the Act

and the regulations applicable to poultry products, if they comply with the conditions specified in this section.

(a) Any human food product (in a consumer package) not provided for in paragraph (c) of this section, if:

(1) It contains less than 2 percent cooked poultry meat (deboned white or dark poultry meat, or both) and/or ''Mechanically Separated (Kind of Poultry)'' as defined in § 381.173;

(2) It contains less than 10 percent of cooked poultry skins, giblets, or fat, separately, and less than 10 percent of cooked poultry skins, giblets, fat, and meat (as meat is limited in paragraph (a)(1) of this section) or ''Mechanically Separated (Kind of Poultry)'' as defined in § 381.173, in any combination;

(3) The poultry ingredients used in the product were prepared under inspection as defined in § 381.1, or were inspected under a foreign inspection system approved under § 381.196(b) and imported in compliance with the Act and the regulations;

(4) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(5) The product is not represented as a poultry product. The aforesaid percentages of ingredients shall be computed on the basis of the moist, deboned, cooked poultry in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) Any human food product (in an institutional pack), not provided for in paragraph (c) of this section, if:

(1) It is prepared for sale only to institutional users, such as hotels, restaurants, and boardinghouses, for use as a soup base or flavoring;

(2) It contains less than 15 percent cooked poultry meat (deboned white or dark poultry meat or both) and/or ''Mechanically Separated (Kind of Poultry)'' as defined in § 381.173, computed on the basis of the moist deboned, cooked poultry meat and/or ''Mechanically Separated (Kind of Poultry)'' in such product; and

(3) It complies with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects.

(c) Bouillon cubes, poultry broths, gravies, sauces, seasonings, and flavorings if:

(1) They contain poultry meat and/or ''Mechanically Separated (Kind of Poultry)'' as defined in § 381.173 or poultry fat only in condimental quantities;

(2) They comply with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects; and

(3) In the case of poultry broth, it will not be used in the processing of any poultry product in any official establishment.

(d) Fat capsules and sandwiches containing poultry products if they comply with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects.

(e) Products of the types specified in this section except those specified in paragraphs (c) and (d) of this section will be deemed to be represented as poultry products if the kind name of the poultry (chicken, turkey, etc.) is used in the product name of the product without appropriate qualification. For example, a consumer-packaged noodle soup product containing less than 2 percent chicken meat on a ready-to-serve basis may not be labeled ''Chicken Noodle Soup'' but, when appropriate, could be labeled as ''Chicken Flavored Noodle Soup.'' Products exempted under this section are subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55982, Nov. 3, 1995]

Subpart D—Application for Inspection; Grant or Refusal of Inspection

§ 381.16 How application shall be made.

The operator of each establishment of the kind required by § 381.6 to have inspection shall make application to the Administrator for inspection service. In cases of change of name, ownership, or location, a new application shall be made.

§ 381.17 Filing of application.

Every application for inspection at any establishment shall be made by the operator on a form furnished by the

Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, and shall include all information called for by that form, including the name of any subsidiary corporation that will prepare any poultry product or conduct any other operation at the establishment for which inspection is requested. The applicant for inspection will be held responsible for compliance by all its subsidiaries with the requirements of the regulations at such establishments if inspection is granted. Processing of poultry products and other operations at the establishment for which inspection is granted may be conducted only by the applicant, except that such a subsidiary of the grantee, may conduct such operations at such establishment.

§ 381.18 Authority of applicant.

Any person applying for inspection service may be required at the discretion of the Administrator to demonstrate that the operator of the establishment authorized him to do so.

§ 381.20 Survey and grant of inspection.

(a) Before inspection is granted, FSIS shall survey the establishment to determine if the construction and facilities of the establishment are in accordance with the regulations. FSIS will grant inspection, subject to §381.21, when these requirements are met.

(b) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

[62 FR 45026, Aug. 25, 1997]

§ 381.21 Refusal of inspection.

(a) Any application for inspection in accordance with this part may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(b)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters of the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended, to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency, or the Administrator of the Environmental Protection Agency to act on a request for certification within 1 year after receipt of such request. Further, upon receipt of an application for inspection and a certification as required by subsection 21(b) of the Federal Water Pollution Control Act, the Administrator (as defined in §381.1) is required by paragraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that paragraph. No grant of inspection can be made until the requirements of said paragraph (2) have been met.

(2) However, certification under subsection 21(b) of the Federal Water Pollution Control Act is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3–year period immediately following April 3, 1970. Failure to obtain such certification or to meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

(3) Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(4) In the case of any activity which will affect water quality but for which there are no applicable water quality standards, no certification is required prior to the grant of inspection but

such grant will be conditioned upon a requirement of compliance with the purpose of the Federal Water Pollution Control Act as provided in paragraph 21(b)(9) of said Act.

[37 FR 9706, May 16, 1972, as amended at 64 FR 66545, Nov. 29, 1999]

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an official establishment or an official import inspection establishment, must have developed written Sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, in accordance with §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4 of this chapter.

[61 FR 38866, July 25, 1996, as amended at 77 FR 26936, May 8, 2012; 79 FR 56233, Sept. 19, 2014]

Subpart E—Inauguration of Inspection; Official Establishment Numbers; Separation of Establishments and Other Requirements; Withdrawal of Inspection

§ 381.25 Official establishment numbers.

An official establishment number shall be assigned to each establishment granted inspection service. Such number shall be used to identify all containers of inspected poultry products prepared in the establishment. An establishment shall not have more than one establishment number.

§ 381.26 Separation of establishments.

Each official establishment shall be separate and distinct from any other official establishment and from any unofficial establishment except an establishment preparing meat products under the Federal Meat Inspection Act or under State meat inspection. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe.

§ 381.27 Inauguration of service; notification concerning regulations; status of uninspected poultry products.

The inspector in charge or his supervisor shall, upon or prior to the inauguration of service, inform the operator of the establishment of the requirements of the regulations. If the establishment at the time service is inaugurated contains any poultry product which has not been inspected and marked in compliance with the regulations, its identity shall be maintained, and it shall not be represented or dealt with as a product which has been inspected. Such products may not be shipped in commerce unless such products are eligible for such shipment under an exemption from inspection under subpart C and comply with all requirements of said subpart.

§ 381.28 Report of violations.

Each inspector, agent, representative, or employee of the Inspection Service shall report, in the manner prescribed by the Administrator, all violations of the Act and noncompliance with the regulations of which he has knowledge.

Subpart F—Assignment and Authorities of Program Employees; Appeals

§§ 381.30–381.31 [Reserved]

§ 381.32 Access to establishments.

[See § 300.6 of this chapter regarding access to establishments and other places of business.]

[69 FR 255, Jan. 5, 2004]

§ 381.33 Identification.

Each inspector will be furnished with a numbered official inspection badge, which shall remain in his or her possession at all times, and which shall be worn in such manner and at such times as the Administrator may prescribe.

[59 FR 42156, Aug. 17, 1994, as amended at 69 FR 255, Jan. 5, 2004]

§ 381.34 Financial interest of inspectors.

(a) No inspector shall inspect any poultry or poultry product in which he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person with whom he is negotiating or has any arrangement concerning prospective employment, is financially interested.

(b) All inspectors are subject to statutory restrictions with respect to political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes referenced in paragraph (b) of this section will constitute grounds for dismissal in the case of appointees and for revocation of licenses in the case of licensees.

(d) Inspectors are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service and other authority concerning employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

§ 381.35 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided*, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal, and such superior shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

[48 FR 11419, Mar. 18, 1983, as amended at 60 FR 67456, Dec. 29, 1995]

Subpart G—Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

§ 381.36 Facilities required.

(a) *Inspector's Office.* Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors'

outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) *Facilities for ante mortem inspection.* A suspect pen is required for adequate ratite inspection.

(c) Facilities for the Streamlined Inspection System (SIS). The following requirements for lines operating under SIS are in addition to the normal requirements to obtain a grant of inspection. The requirements for SIS in § 381.76(b) also apply.

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (c)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 4 feet along the conveyor line for the inspector, and 4 feet for the establishment helper. A total of at least 8 feet along the conveyor line shall be supplied for one inspection station and 16 feet for two-inspection stations.

(iii) Selectors or ''kickouts'' shall be installed in establishments with two inspection stations on a line so each inspector will receive birds on 12-inch centers with no intervening birds to impede inspection. The selector must move the bird to the edge of the trough for the inspector and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid swinging when entering the inspection station.

(iv) Each inspector's station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index value of 85 where the birds are inspected to facilitate inspection.

(viii) Online handrinsing facilities with a continuous flow of water must be provided for and within easy reach of each inspector and each establishment helper. The hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such inspection stations at a minimum temperature of 65 degrees F.

(ix) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(x) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

(2) The following provisions shall apply only to prechill and postchill reinspection stations:

(i) Floor space shall consist of a minimum of 3 feet along each conveyor

line and after each chiller to allow carcasses to be removed for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 2 feet wide, 2 feet deep, and 3 feet high designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index of 85 on the table surface shall be provided.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy access of persons working at the stations.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(d) Facilities for the New Line Speed (NELS) inspection system. The following requirements for lines operating under the NELS inspection system are in addition to the normal requirements to obtain a grant of inspection and to the requirements for NELS in § 381.76 (b) and (c).

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (d)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 6 feet along the conveyor line for the establishment employee presenting the birds, 4 feet for the inspector, and 4 feet for the establishment helper. A total of at least 42 feet along the conveyor line shall be supplied for three inspection stations.

(iii) Selectors or ''kickouts'' shall be installed so the three inspection stations will receive birds on 18-inch centers with no intervening birds to impede inspection. The selector must move the bird to the end of the trough for the presenter, inspector, and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid splashing the mirror (paragraph (d)(1)(vii) of this section) and swinging when entering the inspection station. Guide bars shall not extend in front of the inspection station mirror to avoid obstructing the inspector's view.

(iv) Each inspector's station shall have an easily and rapidly adjustable platform, with a minimum of 14 inches of vertical adjustment, which covers the entire length of the station (4 feet) and has a minimum width of 2 feet. The platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A distortion-free mirror, at least 3 feet wide and 2 feet high, shall be mounted at each inspection station so that it can be adjusted between 5 and 15 inches behind the shackles, tilt up and down, tilt from side to side, and be raised and lowered. The mirror shall be positioned in relation to the inspection platform so that the inspector can position himself/herself opposite it 8 to 12 inches from the downstream edge. The mirror must be maintained abrasion free.

(viii) A minimum of 200-footcandles of shadow-free lighting with minimum color rendering index value of 85[1]

[1] This requirement may be met by deluxe cool white type of fluorescent lighting.

the birds are inspected to facilitate inspection. A light shall also be positioned above and slightly in front of the mirror to facilitate the illumination of the bird and mirror surfaces.

(ix) ''One-line'' handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment presenter and helper.

(x) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(xi) Each inspection station shall be provided with receptacle for condemned carcasses and parts. Such receptacles shall comply with the performance standards in §416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of 6 feet along the conveyor line. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 3 feet wide and 2 feet deep, shall be provided for reinspecting the sample birds.

(iv) A minimum of 200-footcandles of shows free lighting with a minimum color rendering index of 85[1] on the table surface.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(e) Facilities for the New Turkey Inspection (NTI) System. The following requirements for lines operating under the NTI System are in addition to the normal requirements to obtain a grant of inspection and to the requirements for the NTI System in §381.76 (b) and (c).

(1) The following provisions apply to every inspection station:

(i) The conveyor line must be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (e)(1)(iii) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 8 feet along the conveyor line; at least 4 feet for the inspector, and at least 4 feet for the establishment helper.

(iii) The inspector's station shall have an easily and rapidly adjustable platform with a minimum width of 2 feet which covers the entire length of the station (4 feet). The platform must adjust vertically a minimum of 14 inches, and must have a 42-inch rail on the back side and ½-inch foot bumpers on the sides and the front to allow safe working conditions.

(iv) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(v) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be wide enough to prevent trimmings, drippage, and debris from accumulation on the floor or platforms. The clearance between suspended carcasses and the trough must be sufficient to prevent contamination of carcasses by splash.

(vi) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index value of 85[1] where the birds are inspected to facilitate inspection is required. The minimum lighting requirement for inspection stations in §381.52(b) shall not apply.

(vii) On-line handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment helper.

(viii) Hangback racks shall be provided for and within easy reach of the establishment helper.

[1] This requirement may be met by deluxe cool white fluorescent lighting.

(ix) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in §416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of a minimum of 3 feet along the conveyor line so carcasses can be removed from each line for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iii) A table at least 3 feet wide and 2 feet deep designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85[1] at the table surface is required.

(v) A clipboard holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at this station.

(f) *Facilities for post-mortem inspection under the New Poultry Inspection System.* The following facilities requirements apply to establishments operating under the New Poultry Inspection System and are in addition to the requirements for obtaining a grant of inspection.

(1) The following provisions apply to the online carcass inspection station:

(i) On each production line, at a point before the chiller and after the establishment has completed all sorting, trimming, and reprocessing activities necessary to comply with §381.76(b)(6)(ii), at least 4 feet of floor space along the conveyor line must be provided for one online carcass inspection station.

(ii) The conveyor line must be level for the entire length of the online carcass inspection station. The vertical distance from the bottom of the shackles to the top of the platform (paragraph (f)(1)(iii) of this section) must not be less than 60 inches.

(iii) Each online carcass inspection station must have a platform that is slip-resistant and can be safely accessed by the inspector. The platform must be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform must be a minimum length of 4 feet and have a minimum width of 2 feet. The platform must be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(iv) Conveyor line stop/start switches must be located within easy reach of the online carcass inspector.

(v) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index value of 85 must be provided where the birds are inspected to facilitate online carcass inspection.

(vi) Hand rinsing facilities must be provided for use by and within easy reach of the online carcass inspector. The hand rinsing facilities must have a continuous flow of water or be capable of being immediately activated and deactivated in a hands-free manner, must minimize any splash effect, and must otherwise operate in a sanitary manner that prevents contamination of carcasses and inspector clothing. The hand rinsing facilities must provide water at a temperature between 65 and 120 degrees Fahrenheit.

(vii) A separate clipboard holder for holding recording sheets must be provided for and within easy reach of the online carcass inspector.

(viii) Receptacles for condemned carcasses and parts that comply with the performance standards in §416.3(c) of this chapter must be provided at each online carcass inspection station.

(ix) Hangback racks designed to hold at least 10 carcasses must be provided and positioned within easy reach of the online carcass inspector.

(x) A buzzer shall be located within easy reach of the online carcass inspector to be used by the carcass inspector to alert the inspector-in-charge, offline inspectors, or establishment management of conditions that require their attention.

(2) The following provisions apply to pre-chill and post-chill offline verification inspection stations:

(i) One or more offline verification inspection stations must be located at the end of the line or lines prior to the chiller. One or more offline verification inspection stations must also be located after the chiller or chillers. The Agency will determine the total number of offline verification inspection stations needed in establishments having more than one processing line or more than one chiller.

(ii) Floor space for all offline verification inspection stations must consist of a minimum of 3 feet along each conveyor line and after each chiller, as applicable, to allow carcasses to be removed for evaluation by the verification inspector. The space must be level and protected from all traffic and overhead obstructions.

(iii) At the pre-chill location, the vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iv) At each offline verification inspection station, a table designed to be readily cleanable and drainable must be provided for offline verification inspectors to conduct offline verification activities. At turkey slaughter establishments, the table must be at least 3 feet wide, 2 feet deep, and 3 feet high. At all other poultry slaughter establishments, the table must be at least 2 feet wide, 2 feet deep, and 3 feet high

(v) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85 on the table surface must be provided.

(vi) The establishment must provide a separate clipboard holder for holding recording sheets; or alternatively, the establishment may provide electronic means for the offline verification inspector to record inspection results.

(vii) Hangback racks designed to hold at least 10 carcasses must be provided and positioned within easy reach of the offline verification inspector.

(viii) Hand washing facilities must be provided within easy access of all offline verification inspection stations.

(3) Each young chicken establishment operating under the New Poultry Inspection System must provide a location at a point along the production line after the carcasses are eviscerated at which an inspector may safely and properly inspect for leukosis the first 300 carcasses of each flock together with associated viscera either uniformly trailing or leading, or otherwise identified with the corresponding carcass. The leukosis inspection area must provide a minimum of 200 foot-candles of shadow-free lighting on the surface where the viscera are inspected.

(4) A trough or other similar drainage facility must extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splashing.

[37 FR 9706, May 16, 1972, as amended at 38 FR 9794, Apr. 20, 1973; 47 FR 23434, May 28, 1982; 49 FR 42554, Oct. 23, 1984; 50 FR 37512, Sept. 16, 1985; 52 FR 39209, Oct. 21, 1987; 64 FR 56416, Oct. 20, 1999; 66 FR 22905, May 7, 2001; 79 FR 49633, Aug. 21, 2014]

§ 381.37 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of an Inspection Service employee. All eviscerating of poultry and further processing shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall

not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 hours per shift during the basic workweek subject to the provisions of § 381.38: *Provided,* That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday. The 8-hour day excludes the lunch period but shall include activities deemed necessary by the Agency to fully carry out an inspection program, including the time for FSIS inspection program personnel to put on required gear, pick up required forms and walk to a work station; and the time for FSIS inspection program personnel to return from a work station, drop off required forms, and remove required gear; and to conduct duties scheduled by FSIS, including administrative duties. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its functions. These provisions are applicable to all official establishments except in certain cases as provided in § 381.145(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take in account the efficient and effective use of inspection personnel. The work schedule must specify the workweek, daily clock hours of operation, and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving changes in the workweek or an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided, however*, Minor deviations from a daily operating schedule may be approved by the inspector in charge if such request is received on the day preceding the day of change.

(3) Requests for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided*, That an inspector may be recalled to his assignment after the completion of his daily tour of duty under the provisions of § 381.39(b).

[40 FR 45800, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986; 76 FR 33980, June 10, 2011; 77 FR 59294, Sept. 27, 2012]

§ 381.38 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the

fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall be the holiday.

[40 FR 45801, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 51513, Dec. 18, 1985; 52 FR 5, Jan. 2, 1987; 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 381.39 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 381.38(a) and at the rate specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Inspection Service employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of an Inspection Service employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45801, Oct. 3, 1975, as amended at 54 FR 6390, Feb. 10, 1989]

Subpart H—Attestation on Work-Related Conditions

SOURCE: 79 FR 49634, Aug. 21, 2014, unless otherwise noted.

§ 381.45 Attestation requirements.

Each establishment that participates in the New Poultry Inspection System (NPIS) shall submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers, and that the program includes the following elements:

(a) Policies to encourage early reporting of symptoms of injuries and illnesses, and assurance that it has no policies or programs in place that would discourage the reporting of injuries and illnesses.

(b) Notification to employees of the nature and early symptoms of occupational illnesses and injuries, in a manner and language that workers can understand, including by posting in a conspicuous place or places where notices to employees are customarily posted, a copy of the FSIS/OSHA poster encouraging reporting and describing reportable signs and symptoms.

(c) Monitoring on a regular and routine basis of injury and illness logs, as well as nurse or medical office logs, workers' compensation data, and any other injury or illness information available.

§ 381.46 Severability.

Should a court of competent jurisdiction hold any provision of this part 381, subpart H to be invalid, such action shall not affect any other provision of this part 381.

Subpart I—Operating Procedures

§ 381.65 Operations and procedures, generally.

(a) Operations and procedures involving the processing, other handling, or storing of any poultry product must be strictly in accord with clean and sanitary practices and must be conducted in a manner that will result in sanitary processing, proper inspection, and the production of poultry and poultry products that are not adulterated.

(b) Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding. Blood from the killing operation must be confined to a relatively small area.

(c) When thawing frozen ready-to-cook poultry in water, the establishment must use methods that prevent adulteration of, or net weight gain by, the poultry.

(d) The water used in washing the poultry must be permitted to drain freely from the body cavity.

(e) Detached ova may be collected for human food and handled only in accordance with 9 CFR 590.44 and may leave the establishment only to be moved to an official egg product processing plant for processing. Ova from condemned carcasses must be condemned and treated as required in § 381.95.

(f) *Procedures for controlling visible fecal contamination.* Official poultry slaughter establishments must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

(g) *Procedures for controlling contamination throughout the slaughter and dressing operation.* Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. At a minimum, these procedures must include sampling and analysis for microbial organisms in accordance with the sampling location and frequency requirements in paragraphs (g)(1) and (2) of this section to monitor their ability to maintain process control.

(1) *Sampling locations.* Establishments, except for very small establishments operating under Traditional Inspection or very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the pre-chill and post-chill points in the process. Very small establishments operating under Traditional Inspection and very low volume establishments operating under Traditional Inspection must collect and analyze samples for microbial organisms at the post-chill point in the process.

(i) Very small establishments are establishments with fewer than 10 employees or annual sales of less than $2.5 million.

(ii) Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squabs.

(2) *Sampling frequency.* (i) Establishments, except for very low volume establishments as defined in paragraph (g)(1)(ii) of this section, must, at a minimum, collect and analyze samples at a frequency proportional to the establishment's volume of production at the following rates:

(A) *Chickens.* Once per 22,000 carcasses, but a minimum of once during each week of operation.

(B) *Turkeys, ducks, geese, guineas, and squabs.* Once per 3,000 carcasses, but at a minimum once each week of operation.

(ii) Very low volume establishments as defined in paragraph (g)(1)(ii) of this section must collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, a very low volume establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan.

(iii) Establishments must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens. Establishments must maintain accurate records of all test results and retain these records as provided in paragraph (h) of this section.

(h) *Recordkeeping requirements.* Official poultry slaughter establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required under paragraph (g) of this section. Records required by this section may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records required by this section must be maintained for at least one year and must be accessible to FSIS.

[66 FR 1771, Jan. 9, 2001; 66 FR 19714, Apr. 17, 2001, as amended at 79 FR 49634, Aug. 21, 2014]

§ 381.66 Temperatures and chilling and freezing procedures.

(a) *General.* Temperatures and procedures that are necessary for chilling

and freezing ready-to-cook poultry, including all edible portions thereof, must be in accordance with operating procedures that ensure the prompt removal of the animal heat, preserve the condition and wholesomeness of the poultry, and assure that the products are not adulterated.

(b) *Chilling performance standards, except for ratites.* (1)(i) Each official poultry slaughter establishment must ensure that all poultry carcasses, parts, and giblets are chilled immediately after slaughter operations so that there is no outgrowth of pathogens, unless such poultry is to be frozen or cooked immediately at the official establishment.

(ii) Previously chilled poultry carcasses and major portions must be kept chilled so that there is no outgrowth of the pathogens, unless such poultry is to be packed and frozen immediately at the official establishment.

(2) After product has been chilled, the establishment must prevent the outgrowth of pathogens on the product as long as the product remains at the establishment.

(3) The establishment must develop, implement, and maintain written procedures for chilling that address, at a minimum, the potential for pathogen outgrowth, the conditions affecting carcass chilling, and when its chilling process is completed. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOP, or other prerequisite program.

(c) *Ice and water chilling.* (1) Only ice produced from potable water may be used for ice and water chilling, except that water and ice used for chilling may be reused in accordance with § 416.2(g). The ice must be handled and stored in a sanitary manner.

(2)(i) Poultry chilling equipment must be operated in a manner consistent with meeting the applicable pathogen reduction performance standards for raw poultry products as set forth in § 381.94 and the provisions of the establishment's HACCP plan.

(ii) Major portions of poultry carcasses, as defined in § 381.170(b)(22), may be chilled in water and ice.

(d) *Water absorption and retention.* (1) Poultry washing, chilling, and draining practices and procedures must be such as will minimize water absorption and retention at time of packaging.

(2) The establishment must provide scales, weights, identification devices, and other supplies necessary to conduct water tests.

(e) *Air chilling.* Air chilling is the method of chilling raw poultry carcasses and parts predominately with air. An antimicrobial intervention may be applied with water at the beginning of the chilling process, provided that its use does not result in any net pick-up of water or moisture during the chilling process. The initial antimicrobial intervention may result in some temperature reduction of the product, provided that the majority of temperature removal is accomplished exclusively by chilled air.

(f) *Freezing.* (1) Ready-to-cook poultry which is to be or is labeled with descriptive terms such as ''fresh frozen,'' ''quick frozen'' or ''frozen fresh'' or any other term implying a rapid change from a fresh state to a frozen state shall be placed into a freezer within 48 hours after initial chilling in accordance with paragraph (b) of this section. During this period, if such poultry is not immediately placed into a freezer after chilling and packaging, it shall be held at 36 °F. or lower.

(2) Ready-to-cook poultry shall be frozen in a manner so as to bring the internal temperature of the birds at the center of the package to 0 °F. or below within 72 hours from the time of entering the freezer. Such procedures shall not apply to raw poultry product described in § 381.129(b)(6)(i) of this subchapter.

(3) Upon written request, and under such conditions as may be prescribed by the Administrator, in specific cases, ready-to-cook poultry which is to be frozen immediately may be moved from the official establishment prior to freezing: *Provided,* That the plant and freezer are so located and such necessary arrangements are made that the Inspection Service will have access to the freezing room and adequate opportunity to determine compliance with the time and temperature requirements specified in paragraph (f)(2) of this section.

(4) Warm packaged ready-to-cook poultry which is to be chilled by immediate entry into a freezer within the official establishment shall within 2 hours from time of slaughter be placed in a plate freezer or a freezer with a functioning circulating air system where a temperature of −10 °F. or lower is maintained.

(5) Frozen poultry shall be held under conditions which will maintain the product in a solidly frozen state with temperature maintained as constant as possible under good commercial practice.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4568, 4569, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 49 FR 9411, Mar. 13, 1984; 60 FR 44412, Aug. 25, 1995; 63 FR 48960, Sept. 11, 1998; 66 FR 1771, Jan. 9, 2001; 66 FR 19714, Apr. 17, 2001; 66 FR 22905, May 7, 2001; 79 FR 49634, Aug. 21, 2014]

§ 381.67 Young chicken and squab slaughter inspection rate maximums under traditional inspection procedure.

The maximum number of birds to be inspected by each inspector per minute under the traditional inspection procedure for the different young chicken and squab slaughter line configurations are specified in the following table. These maximum rates will not be exceeded. The inspector in charge will be responsible for reducing production line rates where in the inspector's judgment the prescribed inspection procedure cannot be adequately performed within the time available, either because the birds are not presented by the official establishment in such a manner that the carcasses, including both internal and external surfaces and all organs, are readily accessible for inspection, or because the health conditions of a particular flock dictate a need for a more extended inspection procedure. The standards in 381.170(a) of this part specify which classes of birds constitute young chickens and squabs. Section 381.76(b) specifies when either the traditional inspection procedure or the modified traditional inspection procedure can or must be used.

MAXIMUM PRODUCTION LINE RATES—CHICKENS AND SQUABS-TRADITIONAL INSPECTION PROCEDURES

Line configuration [1]	Number of inspection stations	Birds per inspector per minute
6–1	1	25
12–1	2	23
12–2	2	21
18–1	3	19
18–2	3	19
18–3	3	18
24–1	4	16½
24–2	4	16
24–4	4	15½

[1] Birds are suspended on the slaughter line at 6–inch intervals. The first number indicates the interval in inches between the birds that each inspector examines. The second number indicates how many of the birds presented, the inspector is to inspect, i.e., "1" means inspect every bird. "4" means inspect every fourth bird, etc.

[47 FR 23435, May 28, 1982, as amended at 66 FR 22905, May 7, 2001]

§ 381.68 Maximum inspection rates—New turkey inspection system.

(a) The maximum inspection rates for one inspector New Turkey Inspection (NTI–1 and NTI–1 Modified) and two inspectors New Turkey Inspection (NTI–2 and NTI–2 Modified) are listed in the table below. The line speeds for NTI–1 and NTI–2 are for lines using standard 9-inch shackles on 12-inch centers with birds hung on every shackle and opened with J-type or Bar-type opening cuts. The line speeds for NTI–1 Modified and NTI–2 Modified are for Bar-type cut turkey lines using a shackle with a 4-inch by 4-inch selector (or kickout), a 45 degree bend of the lower 2 inches, an extended central loop portion of the shackle that lowers the abdominal cavity opening of the carcasses to an angle of 30 degrees from the vertical in direct alignment with the inspector's view, and a width of 10.5 inches. Maximum rates for those establishments having varying configurations will be established by the Administrator but will not exceed those in the table. Neither the rates in the table nor those established for establishments with varying configurations shall be exceeded under any circumstances.

(b) There are two categories of turkeys for determining inspection rates, ''light turkeys'' and ''heavy turkeys''. Light turkeys are all turkeys weighing

less than 16 pounds. Heavy turkeys are all turkeys weighing 16 pounds or more. The weights refer to the bird at the point of post-mortem inspection, with blood, feathers and feet removed.

(c) The inspector in charge may reduce inspection line rates when in his/her judgment the prescribed inspection procedure cannot be adequately performed within the time available because the health conditions of a particular flock or other factors, including the manner in which birds are being presented to the inspector for inspection and the level of contamination among the birds on the line, dictate a need for a more extended inspection.

MAXIMUM TURKEY INSPECTION RATES

Inspection system	Line configuration	Number of inspectors	Birds/minute			
			J-Type		Bar-Type	
			(<16#) light	(>16#) [1] heavy	(<16#) light	(>16#) [1] heavy
NTI–1	12–1	1	32	30	25	21
NTI–2	[2] 24–2	2	51	41	45	35
NTI–1 Modified	12–1	1	—	—	32	30
NTI–2 Modified	[2] 24–2	2	—	—	51	41

[1] This weight refers to the bird at the point of post-mortem inspection without blood or feet.
[2] The turkeys are suspended on the slaughter line at 12-inch intervals with two inspectors each looking at alternating birds at 24-inch intervals.

[50 FR 37512, Sept. 16, 1985, as amended at 73 FR 51902, Sept. 8, 2008]

EDITORIAL NOTE: At 75 FR 27926, May 19, 2010, § 381.68(a) was amended in the second sentence by removing ''10.5'' and adding in its place ''10''; however, the amendment could not be incorporated because ''10.5'' does not exist in that sentence.

§ 381.69 Maximum line speed rates under the New Poultry Inspection System.

(a) The maximum line speed for young chicken slaughter establishments that operate under the New Poultry Inspection System is 140 birds per minute.

(b) The maximum line speed for turkey slaughter establishments that operate under the New Poultry Inspection System is 55 birds per minute.

(c) Notwithstanding paragraphs (a) and (b) of this section, establishments that operate under the New Poultry Inspection System must reduce their line speed as directed by inspectors-in-charge. Inspectors-in-charge are authorized to direct establishments to operate at a reduced line speed when in their judgment a carcass-by-carcass inspection cannot be adequately performed within the time available due to the manner in which the birds are presented to the online carcass inspector, the health conditions of a particular flock, or factors that may indicate a loss of process control.

(d) Establishments operating under the line speed limits authorized in this section shall comply with all other applicable requirements of the laws, including, but not limited to, 29 U.S.C. 654(a).

[79 FR 49635, Aug. 21, 2014]

Subpart J—Ante Mortem Inspection

§ 381.70 Ante mortem inspection; when required; extent.

(a) An ante mortem inspection of poultry shall, where and to the extent considered necessary by the Administrator and under such instructions as he may issue from time to time, be made of poultry on the day of slaughter in any official establishment.

(b) The examination and inspection of ratites will be on the day of slaughter, except:

(1) When it is necessary for humane reasons to slaughter an injured animal at night or on a Sunday or holiday, and the FSIS veterinary medical officer cannot be obtained; or

(2) In low volume establishments, when ante mortem inspection cannot be done on the day of slaughter, and

the birds to be slaughtered have received ante mortem inspection in the last 24 hours, provided the establishment has an identification and control system over birds that have received ante mortem inspection.

[37 FR 9706, May 16, 1972, as amended at 66 FR 22906, May 7, 2001]

§ 381.71 Condemnation on ante mortem inspection.

(a) Birds plainly showing on ante mortem inspection any disease or condition, that under §§ 381.80 to 381.93, inclusive, would cause condemnation of their carcasses on post mortem inspection, shall be condemned. Birds which on ante mortem inspection are condemned shall not be dressed, nor shall they be conveyed into any department of the official establishment where poultry products are prepared or held. Poultry which has been condemned on ante mortem inspection and has been killed or died otherwise shall under the supervision of an inspector of the Inspection Service, be disposed of as provided in § 381.95.

(b) Dead-on-arrival ratites and ratites condemned on ante mortem inspection will be tagged ''U.S. Condemned'' by an establishment employee under FSIS supervision and disposed of by one of the methods prescribed in § 381.95.

(c) All seriously crippled ratites and non-ambulatory ratites, commonly termed ''downers,'' shall be identified as ''U.S. Suspects.''

(d) Ratites exhibiting signs of drug or chemical poisoning shall be withheld from slaughter.

(e) Ratites identified as ''U.S. Suspects'' or ''U.S. Condemned'' may be set aside for treatment. The ''U.S. Suspect'' or ''U.S. Condemned'' identification device will be removed by an establishment employee under FSIS supervision following treatment if the bird is found to be free of disease. Such a bird found to have recovered from the condition for which it was treated may be released for slaughter or for purposes other than slaughter, provided that in the latter instance permission is first obtained from the local, State, or Federal sanitary official having jurisdiction over movement of such birds.

(f) When it is necessary for humane reasons to slaughter an injured ratite at night or Sunday or a holiday, and the Agency veterinary medical officer cannot be obtained, the carcass and all parts shall be kept for inspection, with the head and all viscera except the gastrointestinal tract held by the natural attachment. If all parts are not so kept for inspection, the carcass shall be condemned. If on inspection of a carcass slaughtered in the absence of an inspector, any lesion or other evidence is found indicating that the bird was sick or diseased, or affected with any other condition requiring condemnation of the animal on ante mortem inspection, or if there is lacking evidence of the condition that rendered emergency slaughter necessary, the carcass shall be condemned. Ratites that are sick, dying, or that have been treated with a drug or chemical and presented for slaughter before the required withdrawal period, are not covered by emergency slaughter provisions.

[37 FR 9706, May 16, 1972, as amended at 66 FR 22906, May 7, 2001; 67 FR 13258, Mar. 22, 2002]

§ 381.72 Segregation of suspects on ante mortem inspection.

(a) All birds, except ratites, that on ante mortem inspection do not plainly show, but are suspected of being affected with, any disease or condition that under §§ 381.80 to 381.93 of this Part may cause condemnation in whole or in part on post mortem inspection, shall be segregated from the other poultry and held for separate slaughter, evisceration, and post mortem inspection. The inspector shall be notified when such segregated lots are presented for post mortem inspection, and inspection of such birds shall be conducted separately. Such procedure for the correlation of ante mortem and post mortem findings by the inspector, as may be prescribed or approved by the Administrator, shall be carried out.

(b) All ratites showing symptoms of disease will be segregated, individually tagged as ''U.S. Suspects'' by establishment personnel under FSIS supervision with a serially numbered metal or plastic leg band or tag bearing the term ''U.S. Suspect,'' and held for further examination by an FSIS veterinarian.

Depending upon the findings of the veterinarian's examination, these birds will either be passed for regular slaughter, slaughtered as suspects, withheld from slaughter, or condemned on ante mortem. Those ratites affected with conditions that would be readily detected on post mortem inspection need not be individually tagged on ante mortem inspection with the ''U.S. Suspect'' tag provided that such ratites are segregated and otherwise handled as ''U.S. Suspects.'' All ratites identified as ''U.S. Condemned'' shall be tagged by establishment personnel, under FSIS supervision, with a serially numbered metal or plastic leg band or tag bearing the term ''U.S. Condemned.''

[66 FR 22906, May 7, 2001]

§ 381.73 Quarantine of diseased poultry.

If live poultry, which is affected by any contagious disease which is transmissible to man, is brought into an official establishment, such poultry shall be segregated. The slaughtering of such poultry shall be deferred and the poultry shall be dealt with in one of the following ways:

(a) If it is determined by a veterinary inspector that further handling of the poultry will not create a health hazard, the lot shall be slaughtered separately, subject to ante mortem and post mortem inspection pursuant to the regulations.

(b) If it is determined by a veterinary inspector that further handling of the poultry will create a health hazard, such poultry may be released for treatment under the control of an appropriate State or Federal agency. If the circumstances are such that release for treatment is impracticable, a careful bird-by-bird ante mortem inspection shall be made, and all birds found to be, or which are suspected of being, affected with a contagious disease transmissible to man shall be condemned.

§ 381.74 Poultry suspected of having biological residues.

When any poultry at an official establishment is suspected of having been treated with or exposed to any substance that may impart a biological residue that would make their edible tissues adulterated, they shall, at the option of the operator of the establishment, be processed at the establishment and the carcasses and all parts thereof retained under U.S. Retained tags, pending final disposition in accordance with § 381.80, of this part, and other provisions in subpart K; or they shall be slaughtered at the establishment and buried or incinerated in a manner satisfactory to the inspector. Alternatively, such poultry may be returned to the grower, if further holding is likely to result in their not being adulterated by reason of any residue. The Inspection Service will notify the other Federal and State agencies concerned of such action. To aid in determining the amount of residue present in the poultry, officials of the Inspection Service may permit the slaughter of any such poultry for the purpose of collecting tissues for analysis of the residue. Such analysis may include the use of inplant screening procedures designed to detect the presence of antimicrobial residues in any species of poultry.

[47 FR 41336, Sept. 20, 1982]

§ 381.75 Poultry used for research.

(a) No poultry used in any research investigation involving an experimental biological product, drug, or chemical shall be eligible for slaughter at an official establishment unless the operator of such establishment, the sponsor of the investigation, or the investigator has submitted to the Inspection Service, or the Veterinary Biologics unit of Veterinary Services, Animal and Plant Health Inspection Service of the Department or the Environmental Protection Agency, or the Food and Drug Administration of the Department of Health, Education, and Welfare, data or a summary evaluation of the data which demonstrates that the use of such biological product, drug, or chemical will not result in the products of such poultry being adulterated, and the Administrator has approved such slaughter.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

Subpart K—Post Mortem Inspection; Disposition of Carcasses and Parts

§ 381.76 Post-mortem inspection under Traditional Inspection, the Streamlined Inspection System (SIS), the New Line Speed (NELS) Inspection System, the New Poultry Inspection System (NPIS), the New Turkey Inspection System (NTI), and Ratite Inspection.

(a) A post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in every official establishment. Each carcass, or all parts comprising such carcass, must be examined by an inspector, except for parts that are not needed for inspection purposes and are not intended for human food and are condemned. Each carcass eviscerated shall be prepared as ready-to-cook poultry.

(b)(1) There are six systems of post-mortem inspection: the New Poultry Inspection System (NPIS), which may be used for young chickens and turkeys; the Streamlined Inspection System (SIS) and the New Line Speed Inspection System (NELS), both of which may be used only for broilers and cornish game hens; the New Turkey Inspection (NTI) System, which may be used only for turkeys; Traditional Inspection, which may be used for all poultry, except for ratites; and Ratite Inspection.

(i) The SIS shall be used only for broilers and cornish game hens if:

(*a*) The Administrator determines that SIS will increase inspector efficiency; or

(*b*) The operator requests SIS and the Administrator determines that the system will result in no loss of inspection efficiency.

(ii) The NELS Inspection System shall be used only for broilers and cornish game hens if:

(*a*) The operator requests the NELS Inspection System, and

(*b*) The Administrator determines that the establishment has the intent and capability to operate at line speeds greater than 70 birds per minute, and meets all the facility requirements in § 381.36(d).

(iii) The NTI System shall be used only for turkeys if:

(*a*) The operator requests it, and

(*b*) The Administrator determines that the establishment meets all the facility requirements in § 381.36(e).

(iv) The NPIS may be used for young chickens and turkeys if the official establishment requests to use it and meets or agrees to meet the requirements of paragraph (b)(6) of this section and the Administrator approves the establishment's request. The Administrator may permit establishments that slaughter classes of poultry other than young chickens and turkeys to operate under the New Poultry Inspection System under a waiver from the provisions of the regulations as provided in § 381.3(b).

(v) Traditional Inspection shall be used for turkeys when neither the NTI System nor the NPIS is used. For other classes of poultry, Traditional Inspection shall be used when SIS, NELS, and the NPIS are not used.

(2) Official establishments that operate under Traditional Inspection, SIS, NELS, NTI, or Ratite Inspection must meet the following requirements:

(i) No viscera or any part thereof may be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless its identity with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made.

(ii) Each carcass to be eviscerated must be opened so as to expose the organs and the body cavity for proper examination by the inspector.

(iii) If a carcass is frozen, it must be thoroughly thawed before being opened for examination by an inspector.

(3) The following requirements are applicable to SIS:

(i) *Definitions.* For purposes of this paragraph, the following definitions shall apply:

(*a*) *Cumulative sum (CUSUM).* A statistical concept used by the establishment and monitored by the inspector whereby compliance is determined based on sample results collected over a period of time. For purposes of determining compliance with the finished product standards, the CUSUM is equal to the sum of prior test results plus the weighted result of the current test

minus the tolerance, with the condition that the resulting CUSUM cannot go below zero.

(*b*) *Tolerance number.* A weighted measure that equates to product being produced at a national product quality level. See Table 2.

(*c*) *Action number.* A level reached by the CUSUM where the process is out of control and product action is required by the establishment or the inspector. See Table 2.

(*d*) ''Start number''. A value halfway between zero and the action number. The start number is used to determine the starting CUSUM for the first subgroup of a shift and to reset the CUSUM value if the CUSUM is equal to or greater than the action number. See Table 2.

(*e*) *Subgroup.* A 10-bird sample collected before product enters the chiller and after product leaves the chiller.

(*f*) *Subgroup absolute limit.* The tolerance number plus 5. See Table 2.

(*g*) *Prechill testing.* Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected prior to product entering the chilling system.

(*h*) *Postchill testing.* Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected as the product leaves the chilling system.

(*i*) *Rework.* Reprocessing the product to correct the condition or conditions causing the nonconformances listed in Table 1.

(ii) *General. (a)* Under SIS, one inspector inspects the outside, inside, and viscera of each bird. There may be two inspectors on one processing line, each inspecting every other bird. For the establishment to run its processing line(s) at maximum speed, optimal conditions must be maintained so that inspection may be conducted efficiently. The inspector in charge determines the speed at which each processing line may be operated to permit inspection. A variety of conditions may affect this determination including the health of each flock and the manner in which birds are being presented to the inspector for inspection.

(*b*) SIS may be performed by one inspector (SIS–1) or two inspectors (SIS–2). SIS–1 requires that the establishment provide one inspection station for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation. The maximum line speed for SIS–1 is 35 birds per minute. SIS–2 requires that the establishment provide two inspection stations for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation. The maximum line speed for SIS–2 is 70 birds per minute.

(*c*) Under all inspection systems, including SIS, inspectors conduct postmortem inspection and look for a number of conditions, as specified elsewhere in this subpart, which may indicate adulteration. Adulterated product is condemned and destroyed, except that carcasses and parts which may be made unadulterated by reprocessing (reworking) may be so reprocessed under the supervision of an inspector and reinspected. Under SIS, inspectors also reinspect product by sampling finished birds (both before and after chilling) for nonconformances with finished product standards (see Table 1). If such nonconformances are present at certain statistical levels, it may indicate process difficulties requiring corrective action by the establishment. If the establishment does not take adequate corrective action, the inspector shall initiate corrective actions such as conducting closer post-mortem inspections and requiring reprocessing and reinspection of previously processed carcasses and parts. Thus, SIS is conducted in two phases—a post-mortem inspection phase and a reinspection phase. The following paragraphs describe the inspection requirements (not addressed elsewhere in this subpart) under each.

(iii) *Post-mortem inspection. (a)* Facilities: Each inspection station must comply with the facility requirements in § 381.36(c).

(*b*) Presentation: Each inspector shall be flanked by an establishment employee assigned to be the inspector's helper. The one inspector on the SIS–1 line shall be presented every bird. Each inspector on the SIS–2 line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward

the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented.

(*c*) Disposition: The inspector shall determine which birds shall be salvaged, reprocessed, condemned, retained for disposition by the veterinarian, or allowed to proceed down the line as a passed bird subject to trim and reinspection. Carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming of birds passed subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after all giblets are harvested and prior to reinspection.

(iv) *Reinspection.* (*a*) Facilities: Reinspection stations are required at both the prechill and postchill locations. The Agency will determine the number of stations needed in those establishments having more than one processing line or more than one chiller. One or more prechill reinspection stations shall be conveniently located at the end of the line or lines prior to chilling. One or more postchill stations must be conveniently located at the end of the chiller or chillers. The prechill and postchill reinspection stations must meet the following provisions:

(*1*) Floor space shall consist of 3 feet along each conveyor line. The space shall be level and protected from all traffic and overhead obstructions.

(*2*) A table at least 2 feet wide and 2 feet deep and 3 feet in height designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(*3*) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85 on the table surface.

(*4*) A separate clip board holder shall be provided for holding the recording sheets.

(*5*) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(*b*) Disposition: An inspector shall monitor the establishment's application of the Finished Product Standards program and shall take corrective action including retaining product to prevent adulterated product from leaving the establishment when the inspector determines that the establishment has failed to apply the program as prescribed in paragraph (b)(3)(iv)(*c*) of this section).

(*c*) Finished Product Standards: Finished Product Standards (FPS) are criteria applied to processed birds before and after chill to ensure that the product being produced is consistently wholesome and unadulterated. These criteria consist of nonconformances (listed in Table 1), the incidence of which is determined from 10 bird subgroup samples, reduced to a CUSUM number, and measured against the standards (Table 2). The standards are applied to permit the Agency to estimate when the production process is in control and when it is out of control. The establishment is responsible for maintaining FPS which, in turn, is monitored by the inspector. FPS is applied in two separate parts. The first is called prechill testing. It is designed to ensure that the slaughter and evisceration procedures are in control. Compliance is measured by determining the CUSUM on consecutive 10-bird subgroup samples collected prior to product entering the chilling system. The second part of the FPS is called postchill testing. It is designed to monitor the production through the chill system to ensure that it meets the postchill FPS. This test is independent of the prechill test. Compliance is measured by determining the CUSUM on consecutive 10-bird subgroup samples as they exit the chilling system. When the system is operating within compliance, the establishment applies the FPS to product samples at the prechill reinspection station. Testing time and time between tests are such that birds represented by the test are still within the chiller. If an out-of-compliance condition is found, the

product leaving the chiller is segregated for rework and retested before it may proceed into commerce. A second 10 bird subgroup sample of the birds is taken after they leave the chiller to ensure that the product meets the postchill FPS. Since the product is closer to the end of processing, the controls on releasing reworked product are stricter than controls under prechill testing, again to ensure that no adulterated product enters into commerce.

(*d*) *Prechill testing.* The prechill FPS have been divided into processing and trim categories. The processing category is designed to monitor the output of the dressing and evisceration procedures. The trim category monitors the establishment's ability to remove unwholesome lesions and conditions from inspected and passed carcasses. Each category is monitored independently of the other category using a separate CUSUM for each category.

(*1*) *Actions to be taken when the process is in control.* If the CUSUM is less than the action number and the subgroup absolute limit is not exceeded, the process is judged to be in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Randomly select and record subgroup sampling times for each production unit of time before product reaches the prechill reinspection station on the production line. In no case shall the time between tests exceed 1 hour of production time.

(*B*) Conduct a 10-bird subgroup test at a random time on each poultry slaughter line. These times are preselected by the establishment and available to the inspector prior to the start of the shift/day's operations. All 10 samples of the subgroup shall be collected at the random time.

(*C*) Obtain the weighted value of each nonconformance by multiplying the number recorded for each nonconformance by the ''factor'' in Table 1, sum the total of all the nonconformances, and calculate the CUSUM value for that test.

(*ii*) Inspector Actions. The inspector shall:

(*A*) Select random times for monitoring subgroup tests for each halfshift on the evisceration line. In establishments that have multiple evisceration lines on a production shift, monitor all lines of product at the random times.

(*B*) Collect the subgroup samples to be monitored at preselected times. All 10 samples of the subgroup shall be collected at the random time selected in paragraph (b)(3)(iv)(*d*)(*1*)(*ii*)(*A*) of this section.

(*C*) Conduct the 10-bird monitoring subgroup test.

(*2*) *Actions to be taken when the subgroup absolute limit is exceeded.* If either an inspector or establishment subgroup test exceeds the subgroup absolute limit of tolerance plus 5 (T + 5), the establishment shall determine if any of the immediate past 5 plant prechill subgroups for that category (processing or trim) resulted in a CUSUM above the start number.

(*i*) If all of the past 5 plant prechill subgroups are at or below the start number, the establishment shall immediately conduct a retest subgroup on that category of prechill to determine sample validity. If retest subgroup total equals tolerance or less, the establishment resumes random time testing. If the retest subgroup total exceeds tolerance, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section. In either case, the prechill retest results will be used to calculate CUSUM.

(*ii*) If any of the past 5 plant prechill subgroups resulted in a CUSUM above the start number, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section.

(*3*) *Actions to be taken when a trimmable lesion/condition is found.* If either inspection or plant monitoring finds any trimmable lesion or condition as specified in item B(7) of Table 1 during a prechill subgroup test, the establishment shall immediately conduct an additional prechill subgroup test for the same trimmable lesion/condition category. This is a requirement on the subgroup testing for the prechill trim nonconformance that is in addition to

the CUSUM test described in paragraph (b)(3)(iv)(*d*)(*1*) of this section.

(*i*) If no additional item in the same category is found on retest, the establishment shall resume random time sampling.

(*ii*) If an additional item in the same category is found on retest, the establishment shall proceed as if CUSUM reaches the action number and shall initiate corrective action set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section for this category only.

(*4*) *Actions to be taken when the CUSUM reaches the action number.* Once CUSUM reaches the action number, the process is judged to be not in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Immediately notify the inspector in charge and the production supervisor responsible for the affected evisceration line.

(*B*) Suspend random time prechill testing of the affected nonconformance category (processing or trim). Suspend random time postchill subgroup testing when the processing category is the affected nonconformance category.

(*C*) Conduct subgroup retests on carcasses leaving the chill system. Apply the prechill criteria in Table 1 (A) or (B), depending upon which category caused the action, and apply prechill Finished Product Standards as listed in Table 2 to determine product compliance. In no case shall the time between retests exceed 30 minutes of production time. Apply prechill standard criteria at the postchill location after notifying the establishment's production supervisor. If any of these subgroup retests on product leaving the chill system result in a subgroup total exceeding tolerance, identify for rework subsequent product at the postchill location. All noncomplying product will be brought into compliance prior to release into commerce. Product from the chiller will continue accumulating for rework until a subsequent subgroup test results in a subgroup total equal to or less than tolerance.

(*D*) Conduct additional subgroup tests at the prechill reinspection station to determine the adequacy of production corrective action. If the prechill tests results in a subgroup total exceeding the tolerance, notify the production supervisor. The number of additional tests at the postchill reinspection station using prechill standards is increased as required to include the product in the chiller represented by this additional prechill test.

(*E*) After two consecutive additional prechill subgroup tests result in subgroup totals equal to or less than tolerance:

—Resume random time prechill subgroup testing as set forth in actions to be taken when the process is in control at paragraph (b)(3)(iv)(*d*)(*1*) of this section.

—Identify product entering the chill system that will mark the end of the retest action upon arrival at the postchill sampling location. Such identification may include tagging or empty space in chillers, depending upon the establishment's identification method.

—Once all product identified as needing retesting has arrived at the postchill sampling location, random time postchill FPS testing resumes.

—If two consecutive additional prechill subgroup tests demonstrate process control with subgroup totals equal to or less than tolerance, but they do not cause CUSUM to fall to the start line or below, reset CUSUM at the start number.

(*ii*) Inspector Actions. The inspector shall monitor product and process actions by making spot-check observations to ensure that all program requirements are met.

(*e*) *Postchill testing.* Postchill subgroups shall be collected after the product leaves the chiller but before the product is divided into separate processes. Each bird sampled shall be observed and its conformance measured against the postchill criteria. The subgroup nonconformance weights shall be totaled and the CUSUM calculated by subtracting the tolerance from the sum of the subgroup total and the starting CUSUM.

(*1*) *Actions to be taken when the process is in control.* If the CUSUM is less than the action number and the subgroup absolute limit is not exceeded, the process is judged to be in control.

(*i*) Establishment Actions. The establishment shall conduct a 10-bird subgroup test for each chiller system at a

randomly selected time of production. In no case shall the time between tests exceed 2 hours of production time.

(*ii*) Inspector Actions. The inspector shall:

(*A*) Select random times for postchill monitoring.

(*B*) Monitor each chill system twice per shift.

(*C*) Conduct subgroup tests at preselected random times.

(*2*) *Actions to be taken when the subgroup absolute limit is exceeded.* If either an inspector or establishment subgroup test exceeds the subgroup absolute limit of tolerance plus 5(T + 5), the establishment shall determine if any of the last 5 postchill monitoring subgroups resulted in a CUSUM above the start number.

(*i*) If all of the past 5 postchill monitoring subgroups resulted in a CUSUM at or below the start number, the establishment shall immediately retest a subgroup to determine sample validity. If this retest subgroup total exceeds tolerance, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*e*)(*3*) of this section.

(*ii*) If any of the past 5 postchill monitoring subgroups resulted in a CUSUM above the start number, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*e*)(*3*) of this section.

(*3*) *Actions to be taken when the CUSUM reaches the action number.* Once CUSUM reaches the action number, the process is judged to be not in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Notify the inspector in charge and the production supervisor responsible for product in the chiller.

(*B*) Suspend random time postchill subgroup testing.

(*C*) Immediately conduct an additional postchill subgroup test. If the retest subgroup total exceeds tolerance, the establishment shall identify subsequent product for rework. Product will continue accumulating for rework until a subsequent subgroup test results in a subgroup total equal to or less than tolerance.

(*D*) After two consecutive additional postchill subgroup tests results in subgroup totals equal to or less than tolerance:

—Resume random time postchill subgroup testing as set forth in actions to be taken when the process is in control at paragraph (b)(3)(iv)(*e*)(*1*) of this section.

—If the two consecutive additional postchill subgroup totals equal to or less than tolerance do not cause CUSUM to fall to the start number or below, reset CUSUM at the start number.

(*ii*) Inspector Actions. The inspector shall monitor product and process actions to ensure that program requirements are met.

(v) When the prechill or postchill product has been identified as having been produced when the process was not in control, additional online subgroup testing by the establishment is required to determine its conformance to the standard. If any of the additional plant subgroup testing results in a subgroup total exceeding tolerance, offline product corrective actions must take place. The responsibilities of the establishment and the inspector change depending on the CUSUM.

All corrective actions such as identifying affected product, segregating product, and maintaining control through rework actions are the establishment's responsibility. Corrective actions by the inspector depends upon the establishment's ability to control rework of affected product. If the establishment fails in its responsibilities, the inspector will identify, segregate, and retain affected product to prevent adulterated product from reaching consumers.

(*a*) Offline product. The establishment shall identify the affected product so that it may be segregated and accumulated offline for rework. The inspector shall spot check the establishment's identification, segregation, and control of reworked product to ensure that program requirements are met.

(*b*) Reworked product. Reworked product must be tested by the establishment with a randomly selected subgroup test of the accumulated reworked lot. Before product is released, the random subgroup test must result

in a subgroup total equal to or less than tolerance. If the subgroup test of a reworked lot results in a subgroup total exceeding tolerance, the lot must be reworked again before another subgroup is selected. The following actions are required.

(*1*) Establishment Actions. The establishment shall:

(*i*) Select the random subgroup from throughout the lot only after the total lot has been reworked.

(*ii*) Conduct the subgroup test using the same criteria (prechill or postchill) that resulted in the rework action.

(*iii*) Release the lot if the reworked subgroup test resulted in a subgroup total equal to or less than tolerance.

(*iv*) Identify and control the lot to be reworked if the reworked subgroup total again exceeds tolerance.

(*2*) Inspector Actions: The inspector shall spot check the rework procedure to ensure that plant monitoring and production meet the requirements of the program.

(vi) After the 10 bird subgroup tests are completed, the prechill and postchill processing nonconformances shall be corrected on all bird samples prior to returning the samples to the product flow. Samples with trim nonconformances shall be returned to the trim station for correction prior to their return to the product flow.

TABLE 1—DEFINITIONS OF NONCONFORMANCES

A Processing Nonconformances
1 Extraneous material ≤1/16″ —Include any specks, tiny smears, or stains of material that measure 1/16″ or less in the greatest dimension. Examples: Ingesta, unattached feathers, grease, bile remnants, and/or whole gall bladder or spleen, embryonic yolk, etc. —Factor is one. —1 to 5 = 1 defect: 6 to 10 = 2 defects; 11 or more = 3 defects. A maximum of three incidents per carcass.
2 Extraneous material >1/16″ to 1″ —The same material as line 1, but measuring >1/16″ to 1″ in the longest dimension. —Factor is one. —A maximum of three incidents per carcass.
3 Extraneous material >1″ —The same material as lines 1 to 2, but measuring greater than one inch. —Factor is two. —A maximum of two incidents per carcass.
4 Oil glands remnant—less than two whole glands —Recognizable fragment(s) of one or both oil glands equals one incident. —Factor is one. —Maximum of one incident per carcass.
5 Oil glands—two whole glands —Both whole oil glands with no missing fragments equals one incident. If the oil glands are cut, but no fragment is removed, consider them to be whole. But if even a small fragment is removed, use line 4. —Factor is two. —A maximum of one incident per carcass.
6 Lung ≥1/4″ whole —Any portion less than a whole lung, and equal to or greater than 1/4″ at the greatest dimension, equals one incident. —Factor is one. —A maximum of two incidents per carcass.
7 Lung—whole —Each whole lung equals one incident. —Factor is two. —A maximum of two incidents per carcass.
8 Intestine —Any identifiable portion of the terminal portion of the intestinal tract with a lumen (closed circle) present, or split piece of intestine large enough to be closed to form a lumen. —Factor is five. —A maximum of one incident per carcass.
9 Cloaca —Any identifiable portion of the terminal portion of the intestinal tract with mucosal lining. —Factor is five. —A maximum of one incident per carcass.
10 Bursa of Fabricius —A whole rosebud, or identifiable portion with two or more mucosal folds. —Factor is two. —A maximum of one incident per carcass.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

11 Esophagus
—Any portion of the esophagus with identifiable mocosal lining.
—Factor is two.
—A maximum of one incident per carcass.

12 Crop—partial—with mucosa
—Any portion of the crop that includes the mucosal lining.
—Factor is two.
—A maximum of one incident per carcass.

13 Crop—whole
—Any complete crop.
—Factor is five.
—A maximum of one incident per carcass.

14 Trachea ≤1″
—Identifiable portion of trachea less than or equal to one inch long.
—Factor is one.
—A maximum of one incident per carcass.

15 Trachea >1″
—Identifiable portion of trachea greater than one inch.
—Factor is two.
—A maximum of one incident per carcass.

16 Hair ≥¼″ 26 or more.
—Hair which is one-fourth inch long or longer measured from the top of the follicle to the end of the hair. 26 or more hairs equal one incident.
—Factor is one.
—A maximum of one incident per carcass.

17 Feather and/or Pinfeathers ≤1″
—Attached feathers or protruding pinfeathers less than or equal to one inch long. Scored 5 to 10 per carcass as one incident, 11 to 15 per carcass as two incidents, and 16 or more as three incidents.
—Factor is one.
—A maximum of three incidents per carcass.

18 Feathers >1″
—Attached feathers longer than one inch. Scored 1 to 3 per carcass as one incident 4 to 6 per carcass as two incidents, and 7 or more as three incidents.
—Factor is one.
—A maximum of three incidents per carcass.

19 Long Shank—both condyles covered
—If the complete tibiotarsal joint is covered, it equals one incident.
—Factor is two.
—A maximum of two incidents per carcass.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

B Trim nonconformances

1 Breast blister
—Inflammatory tissue, fluid, or pus between the skin and keel must be trimmed if membrane ''slips'' or if firm nodule is greater than ½″ in diameter (dime size).
—Factor is two.
—A maximum of one incident per carcass.

2 Breast blister—partially trimmed
—All inflammatory tissue, including that which adheres tightly to the keel bone, must be removed.
—Factor is two.
—A maximum of one incident per carcass.

3 Bruise ½″ to 1″
—Blood clumps or clots in the superficial layers of tissue, skin, muscle or loose subcutaneous tissue may be slit and the blood completely washed out. When the bruise extends into the deeper layers of muscle, the affected tissue must be removed. Very small bruises less than ½″ (dime size) and areas showing only slight reddening need not be counted as defects.
—Factor is one.
—A maximum of five incidents per carcass.

4 Bruise >1″
—Same criteria as in line three, but greater than one inch in greatest dimension.
—Factor is two.
—A maximum of three incidents per carcass.

5 Bruise black/green ¼″ to 1″
—Bruises ¼″ to 1″ that have changed from red to a black/blue or green color due to age.
—Factor is two.
—A maximum of three incidents per carcass.

6 Bruise Black/green >1″
—Same as line 5, but measuring greater that 1″ in greatest dimension.
—Factor is five.
—A maximum of two incidents per carcass.

7 Trimmable lesions/Condition
—A trimmable tumor or identifiable portion of a tumor on any part of the carcass.
—Trimmable Synovitis/airsacculitis (saddle/frog) lesions that have not been removed.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

—Lesion/condition subject to removal following an approved cleanout process. Examples: airsacculitis, salpingitis, nephritis, spleen, or liver conditions requiring removal of the kidneys.

Note: All establishments shall develop and maintain a permanent marking system that identifies carcasses with removable lesions/conditions on the inside surfaces. When removable lesions/conditions are identified inside the carcass by the inspector, the helper will be notified to apply the permanent mark. When removable inside lesions/conditions are found on a subgroup sample without the permanent mark, the error is not recorded in line 7. The affected carcass(s) will be hungback for IIC disposition and corrective action.

—Factor is five.

—A maximum of one incident per carcass.

8 Failure to complete task as indicated by marking system.

Example: Synovitis, airsacculitis, inflammatory process, contamination, etc.

—The helper, under the inspector's direction, will apply a mark to the carcass, indicating to the trimmer(s) that specific action must be taken on that carcass. When airsac and kidney cleanout, or synovitis part removal, or carcass removal from the line is not completed, or only partially completed, this occurrence is recorded as one defect.

—Factor is five. It will also be recorded as a line 7 defect for a total factor of 10.

—A maximum of one incident per carcass.

9 Compound fracture

—Any bone fracture (i.e., leg or wing) that has caused an opening through the skin. May be accompanied with a bruise, but not always. Do not count the bruise in line 3 or 4 if it is associated with the compound fracture.

—Factor is two.

—A maximum of three incidents per carcass.

10 Wingtip compound fracture

—Same criteria as line 9, but only for wingtips.

Note: Bruises not associated with the fracture should be recorded in the appropriate lines.

—Factor is one.

—A maximum of two incidents per carcass.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

11 Untrimmed short hock

—When no cartilage of the hock surface is present and no tendons are attached to the bone.

—Factor is two.

—A maximum of two incidents per carcass.

12 Sores, scabs, inflammatory process, etc. ≤½″

—Any defects such as sores, abscesses, scabs, wounds, dermatitis, inflammatory process, that measure less than or equal to ½″ in the greatest dimension.

—Factor is two.

—A maximum of two incidents per carcass.

13 Sores, scabs, inflammatory process, etc. >½″

—Same as line 12, but greatest dimension is greater than ½″, or a cluster of smaller lesions in close proximity >½″, this category also includes turkey leg edema.

—Factor is five.

—A maximum of one incident per carcass.

14 External mutilation

—Mutilation to the skin and/or muscle that is caused by the slaughter, dressing or eviscerating processes. Skinned elbows (bucked wings) do not trim require unless affected wing joint capsule is also opened.

—Factor is one.

—A maximum of three incidents per carcass.

C Postchill nonconformances—(Designed to monitor those nonconformances added to product during the chilling process)

1 Extraneous material ≤1/16″

—Include specks, grease, or unidentifiable foreign material that measure 1/16″ or less in the greatest dimension.

—Example: Ingesta, grease, or unidentifiable foreign material.

—Factor is one.

—3 to 7 = 1 defect; 8 to 12 = 2 defects; 13 or more = 3 defects. A maximum of three incidents per carcass.

2 Extraneous material >1/16″ to 1″

—This includes ingesta, grease, or unidentifiable foreign material measureing >1/16″ to 1″ longest dimension.

—Factor is one.

—A maximum of three incidents per carcass.

3 Extraneous material >1″

—The same material as line 2, but measuring greater than one inch.

—Factor is two.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

—A maximum of two incidents per carcass.

TABLE 2—FINISHED PRODUCT STANDARDS

	SIS
Prechill Processing Nonconformance	
Tolerance number (T)	25
Subgroup Absolute Limit (T + 5)	30
Action number	22
Start number	11
Prechill Trim Nonconformance	
Tolerance number (T)	12
Subgroup Absolute Limit (T + 5)	17
Action number	15
Start number	8
Postchill Nonconformance	
Tolerance number (T)	5
Subgroup Absolute Limit (T + 5)	10
Action number	10
Start number	5

(4) The following requirements are also applicable to NELS inspection:

(i) Inspection under NELS is conducted in two phases, as post-mortem inspection phase and a reinspection phase.

(*a*) *Post-mortem inspection.* The establishment shall provide three inspection stations on each eviscerating line in compliance with the facility requirements §381.36(d)(1). The three inspectors shall inspect the inside, viscera, and outside of all birds presented. Each inspector shall be flanked by two establishment employees—the presenter and the helper. The presenter shall ensure that the bird is properly eviscerated and presented for inspection and the viscera uniformly trailing or leading. The inspector shall determine which birds shall be salvaged, reprocessed, condemned, retained for disposition by the veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Poultry carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming or birds passed subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after giblet harvest and prior to reinspection.

(*b*) A reinspection station shall be located at the end of each line. This station shall comply with the facility requirements in §381.36(d)(2). The inspector shall ensure that the establishment has performed the indicated trimming of carcasses passed subject to reinspection by visually monitoring, checking data, or gathering samples at the station or at other critical points on the line.

(ii)–(iii) [Reserved]

(iv) The maximum inspection rate for NELS shall be 91 birds per minute per eviscerating line.

(5) The following requirements are also applicable to the NTI System:

(i) Inspection under the NTI System is conducted in two phases, a post-mortem inspection phase and a reinspection phase. The NTI–1 Inspection System requires that the establishment provide one inspection station for each line and adequate reinspection facilitiates so carcasses can be removed from each line for evaluation. The NTI–2 Inspection System requires that the establishment provide two inspection stations for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation.

(*a*) *Post-mortem inspection.* Each inspection station must comply with the facility requirements in §381.36(e)(1). Each inspector shall be flanked by and establishment employee assigned to be the inspector's helper. The one inspector on an NTI–1 Inspection System shall be presented every bird. Each inspector on an NTI–2 Inspection System line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented. The inspector shall determine which bird shall be salvaged, reprocessed, condemned, retained for disposition by a veterinarian, or allowed to proceed down the line as a passed bird

subject to reinspection. Turkey carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects of birds passed subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after the giblet harvest and prior to reinspection.

(*b*) *Reinspection.* A reinspection station shall be located at the end of the lines. This station shall comply with the facility requirements in § 381.36(e)(2). The inspector shall ensure that establishments have performed the indicated trimming of each carcass passed subject to reinspection by visually monitoring, checking data, and/or sampling product at the reinspection station and, if necessary, at other points, critical to the wholesomeness of product, on the eviscerating line.

(ii)–(iii) [Reserved]

(6) The following requirements are applicable to the NPIS:

(i) *Facilities.* The establishment must comply with the facilities requirements in § 381.36(f).

(ii) *Carcass sorting and disposition.* (A) The establishment must conduct carcass with associated viscera sorting activities, dispose of carcasses and parts exhibiting condemnable conditions, and conduct appropriate trimming and reprocessing activities before carcasses are presented to the online carcass inspector.

(B) Any carcasses removed from the line for reprocessing activities or salvage must be returned to the line before the online carcass inspection station. The establishment must include in its written HACCP plan, or sanitation SOP, or other prerequisite program a process by which parts, other than parts identified as ''major portions'' as defined in § 381.170(b)(22), are available for inspection offline after reprocessing or salvage.

(C) The establishment must develop, implement, and maintain written procedures to ensure that poultry carcasses contaminated with septicemic and toxemic conditions do not enter the chiller. The establishment must incorporate these procedures into its HACCP plan, or sanitation SOP, or other prerequisite program. These procedures must cover, at a minimum, establishment sorting activities required under paragraph (b)(6)(ii) of this section.

(D) The establishment must maintain records to document that the products resulting from its slaughter operation meet the definition of ready-to-cook poultry in § 381.1. These records are subject to review and evaluation by FSIS personnel.

(iii) *Presentation for online carcass inspection.* To ensure the online carcass inspector may properly inspect every carcass, the establishment must present carcasses as follows:

(A) Each carcass, except carcasses and parts identified as ''major portions'' under 9 CFR 381.179(b)(22), must be held by a single shackle;

(B) Both hocks of each carcass must be held by the shackle;

(C) The back side of the carcass must be faced toward the inspector;

(D) There must be minimal carcass swinging motion;

(E) The establishment must ensure that it can sufficiently identify viscera and parts corresponding with each carcass inspected by the online carcass inspector so that if the carcass inspector condemns a carcass all corresponding viscera and parts are also condemned.

(iv) *Inspection for Avian Visceral Leukosis.* (A) Establishments that slaughter young chickens must notify the inspector-in-charge prior to the slaughter of each new flock to allow the inspection of viscera as provided in § 381.36(f)(3).

(B) If there is evidence that a flock may be affected by avian visceral leukosis, the inspector-in-charge is authorized to adjust inspection procedures as needed to ensure adequate inspection of each carcass and viscera for that condition. The inspector-in-charge

is also authorized to require the establishment to adjust its processing operations as needed to accommodate the adjusted inspection procedures.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0008)

[47 FR 23435, May 28, 1982, as amended at 49 FR 42555, Oct. 23, 1984; 50 FR 37513, Sept. 16, 1985; 50 FR 38097, Sept. 20, 1985; 51 FR 3574, Jan. 29, 1986; 53 FR 46861, Nov. 21, 1988; 62 FR 5143, Feb. 4, 1997; 65 FR 34390, May 30, 2000; 66 FR 22906, May 7, 2001; 79 FR 49635, Aug. 21, 2014]

§ 381.77 Carcasses held for further examination.

Each carcass, including all parts thereof, in which there is any lesion of disease, or other condition which might render such carcass or any part thereof adulterated and with respect to which a final decision cannot be made on first examination by the inspector, shall be held for further examination. The identity of each such carcass, including all parts thereof, shall be maintained until a final examination has been completed.

§ 381.78 Condemnation of carcasses and parts: separation of poultry suspected of containing biological residues.

(a) At the time of any inspection under this subpart each carcass, or any part thereof, which is found to be adulterated shall be condemned, except that any such articles which may be made not adulterated by reprocessing, need not be so condemned if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated.

(b) When a lot of poultry suspected of containing biological residues is inspected in an official establishment, all carcasses and any parts of carcasses in such lot which are condemned shall be kept separate from all other condemned carcasses or parts.

[37 FR 9706, May 16, 1972, as amended at 48 FR 22899, May 23, 1983; 48 FR 23807, May 27, 1983]

§ 381.79 Passing of carcasses and parts.

Each carcass and all organs and other parts of carcasses which are found to be not adulterated shall be passed for human food.

§ 381.80 General; biological residues.

(a) The carcasses or parts of carcasses of all poultry inspected at an official establishment and found at the time of post mortem inspection, or at any subsequent inspection, to be affected with any of the diseases or conditions named in other sections in this subpart, shall be disposed of in accordance with the section pertaining to the disease or condition. Owing to the fact that it is impracticable to formulate rules for each specific disease or conditions and to designate at just what stage a disease process results in an adulterated article, the decision as to the disposal of all carcasses, organs or other parts not specifically covered by the regulations, or by instructions of the Administrator issued pursuant thereto, shall be left to the inspector in charge, and if the inspector in charge is in doubt concerning the disposition to be made, specimens from such carcasses shall be forwarded to the Inspection Service laboratory for diagnosis.

(b) All carcasses, organs, or other parts of carcasses of poultry shall be condemned if it is determined on the basis of a sound statistical sample that they are adulterated because of the presence of any biological residues.

§ 381.81 Tuberculosis.

Carcasses of poultry affected with tuberculosis shall be condemned.

§ 381.82 Diseases of the leukosis complex.

Carcasses of poultry affected with any one or more of the several forms of the avian leukosis complex shall be condemned.

§ 381.83 Septicemia or toxemia.

Carcasses of poultry showing evidence of any septicemic or toxemic disease, or showing evidence of an abnormal physiologic state, shall be condemned.

§ 381.84 Airsacculitis.

Carcasses of poultry with evidence of extensive involvement of the air sacs with airsacculitis or those showing airsacculitis along with systemic

changes shall be condemned. Less affected carcasses may be passed for food after complete removal and condemnation of all affected tissues including the exudate.

[40 FR 14297, Mar. 31, 1975]

§ 381.85 Special diseases.

Carcasses of poultry showing evidence of any disease which is characterized by the presence, in the meat or other edible parts of the carcass, or organisms or toxins dangerous to the consumer, shall be condemned.

§ 381.86 Inflammatory processes.

Any organ or other part of a carcass which is affected by an inflammatory process shall be condemned and, if there is evidence of general systemic disturbance, the whole carcass shall be condemned.

§ 381.87 Tumors.

Any organ or other part of a carcass which is affected by a tumor shall be condemned and when there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor, the whole carcass shall be condemned.

§ 381.88 Parasites.

Organs or other parts of carcasses which are found to be infested with parasites, or which show lesions of such infestation shall be condemned and, if the whole carcass is affected, the whole carcass shall be condemned.

§ 381.89 Bruises.

Any part of a carcass which is badly bruised shall be condemned and, if the whole carcass is affected as a result of the bruise, the whole carcass shall be condemned. Parts of a carcass which show only slight reddening from a bruise may be passed for food.

§ 381.90 Cadavers.

Carcasses of poultry showing evidence of having died from causes other than slaughter shall be condemned.

§ 381.91 Contamination.

(a) Carcasses of poultry contaminated by volatile oils, paints, poisons, gases, scald vat water in the air sac system, or other substances which render the carcasses adulterated shall be condemned. Any organ or other part of a carcass which has been accidentally multilated in the course of processing shall be condemned, and if the whole carcass is affected, the whole carcass shall be condemned.

(b) Any carcass of poultry accidentally contaminated during slaughter with digestive tract contents need not be condemned if promptly reprocessed under the supervision of an inspector and thereafter found not to be adulterated. Contaminated surfaces that are cut must be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming alone or may be re-processed as provided in subparagraph (b)(1) or (2) of this section.

(1) *Online reprocessing.* Poultry carcasses accidentally contaminated with digestive tract contents may be cleaned by applying an online reprocessing antimicrobial intervention to all carcasses after evisceration and before the carcasses enter the chiller if the parameters for use of the antimicrobial intervention system have been approved by the Administrator. Establishments must incorporate procedures for the use of any online reprocessing antimicrobial intervention system into their HACCP plans, or sanitation SOPs, or other prerequisite programs.

(2) *Offline reprocessing.* Contaminated inner surfaces that are not cut may be cleaned at an approved reprocessing station away from the main processing line by any method that will remove the contamination, such as vacuuming, washing, and trimming, singly or in combination. All visible specks of contamination must be removed, and if the inner surfaces are reprocessed other than solely by trimming, all surfaces of the carcass must be treated with chlorinated water containing 20 ppm to 50 ppm available chlorine or another approved antimicrobial substance in accordance with the parameters approved by the Administrator. Establishments must incorporate procedures for the use of any offline reprocessing into their HACCP plans, or

sanitation SOPs, or other prerequisite programs.

[37 FR 9706, May 16, 1972, as amended at 43 FR 12847, Mar. 28, 1978; 79 FR 49636, Aug. 21, 2014]

§ 381.92 Overscald.

Carcasses of poultry which have been overscalded, resulting in a cooked appearance of the flesh, shall be condemned.

§ 381.93 Decomposition.

Carcasses of poultry deleteriously affected by post mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) Any part of a carcass which is green struck shall be condemned and, if the carcass is so extensively affected that removal of affected parts is impracticable, the whole carcass shall be condemned.

(c) Carcasses affected by types of post mortem change which are superficial in nature may be passed for human food after removal and condemnation of the affected parts.

§ 381.94 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards for establishments that slaughter ratites.

(a) *Criteria for verifying process control; E. coli testing.* (1) Each official establishment that slaughters ratites shall test for *Escherichia coli* Biotype I (*E. coli*). Establishments that slaughter ratites and livestock, shall test the type of ratites or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) *Sampling requirements.* (i) *Written procedures.* Each establishment that slaughters ratites shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection.* The establishment must collect samples from whole ratites at the end of the chilling process. Samples from ratites may be collected by sponging the carcass on the back and thigh or samples can be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird.

(iii) *Sampling frequency.* Establishments that slaughter ratites, except very low volume ratite establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rate: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation.

(iv) *Sampling frequency alternatives.* An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) *Sampling in very low volume ratite establishments.* (A) Very low volume ratite establishments annually slaughter no more than 6,000 ratites. Very low volume ratite establishments that slaughter ratites in the largest number must collect at least one sample during each week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June of the following year or until 13 samples have been collected, whichever comes first.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless

changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of colony forming units (CFU)/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) Establishments shall evaluate *E. coli* test results using statistical process control techniques.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a) (1) through (4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) [Reserved]

[61 FR 38866, July 25, 1996, as amended at 62 FR 26218, May 13, 1997; 62 FR 61009, Nov. 14, 1997; 64 FR 66553, Nov. 29, 1999; 67 FR 13258, Mar. 22, 2002; 79 FR 49636, Aug. 21, 2014]

Subpart L—Handling and Disposal of Condemned or Other Inedible Products at Official Establishments

§ 381.95 Disposal of condemned poultry products.

All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishment.)

(a) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, for a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. (Tanks and equipment used for this purpose or for rendering or preparing inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection by means of pipes, or otherwise, between tanks containing inedible products and those containing edible products.)

(b) Incineration or complete destruction by burning.

(c) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(1) Crude carbolic acid,

(2) Kerosene, fuel oil, or used crankcase oil, or

(3) Any phenolic disinfectant conforming to commercial standards CS 70–41 or CS 71–41 which shall be used in at least 2 percent emulsion or solution.

(d) Any other substance or method that the Administrator approves in specific cases, which will denature the

poultry product to the extent necessary to accomplish the purposes of this section.

(e) Carcasses and parts of carcasses condemned for biological residue shall be disposed of in accordance with paragraph (b) of this section or by burying under the supervision of an inspector.

Subpart M—Official Marks, Devices, and Certificates; Export Certificates; Certification Procedures

§ 381.96 Wording and form of the official inspection legend.

Except as otherwise provided in this subpart, the official inspection legend required to be used with respect to inspected and passed poultry products shall include wording as follows: ''Inspected for wholesomeness by U.S. Department of Agriculture.'' This wording shall be contained within a circle. The form and arrangement of such wording shall be exactly as indicated in the example in Figure 1, except that the appropriate official establishment number shall be shown, and if the establishment number appears elsewhere on the labeling material in the manner prescribed in §381.123(b), it may be omitted from the inspection mark. The administrator may approve the use of abbreviations of such inspection mark; and such approved abbreviations shall have the same force and effect as the inspection mark. The official inspection legend, or the approved abbreviation thereof, shall be printed on consumer packages and other immediate containers of inspected and passed poultry products, or on labels to be securely affixed to such containers of such products and may be printed or stenciled thereon, but shall not be applied by rubber stamping. When applied by a stencil, the legend shall not be less than 4 inches in diameter. An official brand must be applied to inspected and passed carcasses and parts of ratites that are shipped unpacked.

FIGURE 1

[66 FR 22906, May 7, 2001]

§ 381.97 [Reserved]

§ 381.98 Official seal.

The official mark for use in sealing means of conveyance used in transporting poultry products under any requirement in this part shall be the inscription and a serial number as shown below, and any seals approved by the Administrator for applying such mark shall be an official device.

FIGURE 3

§ 381.99 Official retention and rejection tags.

The official marks for use in postmortem inspection and identification of adulterated products, insanitary equipment and facilities are:

(a) A paper tag (a portion of Form MP–35) bearing the legend ''U.S. Retained'' for use on poultry or poultry products under this section.

(b) A paper tag (another portion of Form C&MS 510) bearing the legend ''U.S. Rejected'' for use on equipment,

utensils, rooms and compartments under this section.

[64 FR 56417, Oct. 20, 1999]

§ 381.100 Official detention tag.

The detention tag prescribed in § 381.211 is an official device.

§ 381.101 Official U.S. Condemned mark.

The term ''U.S. Condemned'' as shown below is an official mark and the devices used by the Department for applying such mark are official devices.

U.S.
CONDEMNED

FIGURE 4

§ 381.102 [Reserved]

§ 381.103 Official poultry condemnation certificates; issuance and form.

Upon request by the operator of the establishment, the inspector in charge shall issue a poultry condemnation certificate (Form MP–514–1), showing the total number of poultry in the lot and the numbers condemned and the reasons for such condemnations.

The official poultry condemnation certificate authorized by this subpart is a paper certificate (Form MP–514–1), for signature by an inspector, bearing the legend

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POULTRY CONDEMNATION CERTIFICATE

and the seal of the United States Department of Agriculture, with a certification that the poultry enumerated on the form were inspected and condemned for the listed causes in compliance with the regulations of the Department. A statement to the effect that certain figures on the certificate were derived from information supplied by plant management, and a signature line for an authorized plant official is also shown.

§ 381.104 Export inspection marks.

The export inspection mark required in § 381.105 must be either a mark that contains a unique identifier that links the consignment to the export certificate or an official mark with the following form: [1]

[81 FR 42234, June 29, 2016]

§ 381.105 Marking products for export.

When authorized by inspection personnel, establishments must mark the outside container of any inspected and passed product for export, the securely enclosed pallet within the consignment, or closed means of conveyance transporting the consignment, with a mark that contains a unique identifier that links the consignment to the export certificate or an official mark as described in § 381.104. Ship stores, small quantities exclusively for the personal use of the consignee and not for sale or distribution, and shipments by and for the U.S. Armed Forces, are exempt from the requirements of this section.

[81 FR 42234, June 29, 2016]

§ 381.106 Export certification.

(a) Exporters must apply for export certification of inspected and passed products to any foreign country. Exporters may apply for an export certificate using a paper or electronic application. FSIS will assess exporters that submit an electronic application the charge in § 362.5(e) of this chapter.

(b) FSIS will issue only one certificate for each consignment, except in the case of error in the certificate or loss of the certificate originally issued. A request for a replacement certificate,

[1] The number ''1234567'' is given as an example only. The number on the mark will correspond to the printed number on the export certificate.

except in the case of a lost certificate, must be accompanied by the original certificate. The new certificate will carry the following statement: ''Issued in replacement of _____'', with the numbers of the certificates that have been superseded.

(c) FSIS will deliver a copy of the certificate to the person who requested such certificate or his agent. Such persons may duplicate the certificate as required in connection with the exportation of the product.

(d) FSIS will retain a copy of the certificate.

(e) Exporters may request inspection personnel to issue certificates for export consignments of product of official establishments not under their supervision, provided the consignments are first identified as having been ''U.S. inspected and passed,'' are found to be neither adulterated nor misbranded, and are marked as required by § 381.105.

[81 FR 42234, June 29, 2016]

§ 381.107 Special procedures as to certification of poultry products for export to certain countries.

When export certificates are required by any foreign country for poultry products exported to such country, the Administrator shall in specific cases prescribe or approve the form of export certificate to be used and the methods and procedures he deems appropriate with respect to the processing of such products, in order to comply with requirements specified by the foreign country regarding the export products. Inspectors shall satisfy themselves that all such requirements are met before issuing such an export certificate. It shall be the responsibility of the exporter to provide any unofficial documentation needed to meet the foreign requirements, before the export certificate will be issued. Such certificates may also cover articles exempted from definition as a poultry product under § 381.15 if they have been inspected and are certified under the regulations in part 362 of this chapter.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 41 FR 23702, June 11, 1976]

§ 381.108 Official poultry inspection certificates; issuance and disposition.

(a) Upon the request of an interested party, any veterinary inspector is authorized to issue an official poultry inspection certificate with respect to any lot of slaughtered poultry inspected by him. At any official establishment each such certificate shall be signed by the inspector who made the inspection covered by the certificate, and if more than one inspector participated in the inspection of the lot of poultry, each such inspector shall sign the certificate with respect to such lot. If the inspection of a lot covered by a certificate was made by a food inspector, such certificate shall also be signed by the inspector in charge when such inspection was made. Any inspector is authorized to issue a poultry inspection certificate with respect to any other poultry product inspected by him.

(b) The original and one copy of each poultry inspection certificate shall be issued to the applicant who requested such certificate, and one copy shall be retained by the inspector for filing. The inspector who issues any inspection certificate is authorized to furnish an additional copy of such certificate upon the request of an interested party. The person who sold the live poultry involved to the official establishment is an interested party for purposes of this section.

[37 FR 9706, May 16, 1972, as amended at 39 FR 36000, Oct. 7, 1974]

§ 381.109 Form of official poultry inspection certificate.

(a) The official poultry inspection certificate authorized by this subpart is a paper certificate (Form MP–505) for signature by an inspector, bearing the legend

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POULTRY INSPECTION CERTIFICATE

and the seal of the U.S. Department of Agriculture, with a certification that the poultry described therein had been

inspected in compliance with the Regulations of the Secretary of Agriculture Governing the Inspection of Poultry and Poultry Products.

(b) The certificate also bears a serial number such as ''B 3208'' and shows the respective name and address of the applicant, the shipper or seller and the receiver or buyer and the net weight in pounds of amount passed, amount rejected or condemned, type of poultry, lot number and class, and such other information as the Administrator may prescribe or approve in specific cases.

§ 381.110 Erasures or alterations made on certificates.

Erasures or alterations not initialed by the issuing inspector shall not be permitted on any official certificate or any copy thereof. All certificates rendered useless through clerical error or otherwise and all certificates canceled for whatever cause shall be voided and initialed, and one copy shall be retained in the inspector's file; and the original and all other copies shall be forwarded to the appropriate program supervisor.

§ 381.111 Data to be entered in proper spaces.

All certificates shall be so executed that the data entered thereon will appear in the proper spaces on each copy of the certificate.

§ 381.112 Official mark for maintaining the identity and integrity of samples.

The official mark for use in sealing containers of samples submitted under any requirements in this part and section 11(b) of the Poultry Products Inspection Act shall bear the designation ''Sample Seal'' accompanied by the official USDA logo as shown below. Any seal approved by the Administrator for applying such mark shall be deemed an official device for purposes of the Act. Such device shall be supplied to inspectors, compliance officers, and other designated Agency officials by the United States Department of Agriculture.

[52 FR 41958, Nov. 2, 1987]

Subpart N—Labeling and Containers

§ 381.115 Containers of inspected and passed poultry products required to be labeled.

Except as may be authorized in specific cases by the Administrator with respect to shipment of poultry products between official establishments, each shipping container and each immediate container of any inspected and passed poultry product shall at the time it leaves the official establishment bear a label which contains information, and has been approved, in accordance with this subpart.

§ 381.116 Wording on labels of immediate containers.

(a) Each label for use on immediate containers for inspected and passed poultry products shall bear on the principal display panel (except as otherwise permitted in the regulations), the items of information required by this subpart. Such items of information shall be in distinctly legible form. Except as provided in § 381.128, all words, statements and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(b) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions

of display for sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by the regulations with clarity and conspicuousness and without being obscured by design or vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The area that is to bear the principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area on the side of the container that is 40 percent of the product of the height of the container times the circumference, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: *Provided, however,* That there is, immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in §§ 381.118, 381.122, and 381.123. Such panel shall be known as the ''20 percent panel'' and such information may be shown on that panel in lieu of showing it on the principal display panel as provided in this § 381.116.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars.

(c) (1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

[37 FR 9706, May 16, 1972, as amended at 40 FR 11347, Mar. 11, 1975; 59 FR 40214, Aug. 8, 1994]

§ 381.117 Name of product and other labeling.

(a) The label shall show the name of the product, which, in the case of a poultry product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in subpart P, shall be the name of the food specified in the standard, and in the case of any other poultry product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation.

(b) The name of the product required to be shown on labels for fresh or frozen raw whole carcasses of poultry

shall be in either of the following forms: The name of the kind (such as chicken, turkey, or duck) preceded by the qualifying term ''young'' or ''mature'' or ''old'', whichever is appropriate; or the appropriate class name as described in § 381.170(a). The name of the kind may be used in addition to the class name, but the name of the kind alone without the qualifying age or class term is not acceptable as the name of the product, except that the name ''chicken'' may be used without such qualification with respect to a ready-to-cook pack of fresh or frozen cut-up young chickens, or a half of a young chicken, and the name ''duckling'' may be used without such qualification with respect to a ready-to-cook pack of fresh or frozen young ducks. The class name may be appropriately modified by changing the word form, such as using the term ''roasting chicken'', rather than ''roaster.'' The appropriate names for cut-up parts are set forth in § 381.170(b). When naming parts cut from young poultry, the identity of both the kind of poultry and the name of the part shall be included in the product name. The product name for parts or portions cut from mature poultry shall include, along with the part or portion name, the class name or the qualifying term ''mature.'' The name of the product for cooked or heat processed poultry products shall include the kind name of the poultry from which the product was prepared but need not include the class name or the qualifying term ''mature.''

(c) Poultry products containing light and dark chicken or turkey meat in quantities other than the natural proportions, as indicated in Table 1 in this paragraph, must have a qualifying statement in conjunction with the name of the product indicating, as shown in Table 1, the types of meat actually used, except that when the product contains less than 10 percent cooked deboned poultry meat or is processed in such a manner that the character of the light and dark meat is not distinguishable, the qualifying statement will not be required, unless the product bears a label referring to the light or dark meat content. In the latter case, the qualifying statement is required if the light and dark meat are not present in natural proportions. The qualifying statement must be in type at least one-half the size and of equal boldness as the name of the product; e.g., Boned Turkey (Dark Meat).

TABLE 1

Label terminology	Percent light meat	Percent dark meat
Natural proportions	50–65	50–35
Light or white meat	100	0
Dark meat	0	100
Light and dark meat	51–65	49–35
Dark and light meat	35–49	65–51
Mostly white meat	66 or more	34 or less
Mostly dark meat	34 or less	66 or more

(d) Boneless poultry products shall be labeled in a manner that accurately describes their actual form and composition. The product name shall specify the form of the product (e.g., emulsified, finely chopped, etc.), and the kind name of the poultry, and if the product does not consist of natural proportions of skin and fat, as they occur in the whole carcass, shall also include terminology that describes the actual composition. If the product is cooked, it shall be so labeled. For the purpose of this paragraph, natural proportions of skin, as found on a whole chicken or turkey carcass, will be considered to be as follows:

	Percent	
	Raw	Cooked
Chicken	20	25
Turkey	15	20

Boneless poultry product shall not have a bone solids content of more than 1 percent, calculated on a weight basis.

(e) On the label of any ''Mechanically Separated (Kind of Poultry) '' described in § 381.173, the name of such product shall be followed immediately by the phrase: ''with excess skin'' unless such product is made from poultry product that does not include skin in excess of the natural proportion of skin present on the whole carcass, as specified in paragraph (d) of this section. Appropriate terminology on the label shall indicate if heat treatment has been used in the preparation of the product. The labeling information described in this paragraph shall be identified on the label before the product leaves the

establishment at which it is manufactured.

(f) The labels of sausages encased in natural casings made from meat or poultry viscera shall identify the type of meat or poultry from which the casings were derived, if the casings are from a different type of meat or poultry than the encased meat or poultry. The identity of the casing, if required, may be placed on the principal display panel or in the ingredient statement. Establishments producing, manufacturing, or using natural sausage casings are to maintain records documenting the meat or poultry source in accordance with subpart Q of this part.

(g) The labels of sausages encased in regenerated collagen casings shall disclose this fact on the product label. The fact that the sausage is encased in collagen may be placed on the principal display panel or in the ingredient statement.

(h) The product name for a raw poultry product that contains added solution and does not meet a standard of identity in this part must contain a descriptive designation that includes:

(1) The percentage of added solution (total weight of the solution ingredients divided by the weight of the raw poultry without solution or any other added ingredients multiplied by 100). The percentage of added solution must appear as a number (such as, 15, 20, 30) and the percent symbol (%). The percentage of added solution may be declared by the words ''containing'' or ''contains'' (such as, ''contains 15% added solution of water and salt,'' or ''containing 15% added solution of water and teriyaki sauce'').

(2) The common or usual name of all individual ingredients or multi-ingredient components in the solution listed in descending order of predominance by weight.

(3) When the descriptive designation includes all ingredients in the solution, a separate ingredients statement is not required on the label. When the descriptive designation includes multi-ingredient components and the ingredients of the component are not declared in the product name, all ingredients in the product must be declared in a separate ingredients statement on the label as required in § 381.118.

(4) The product name and the descriptive designation must be printed in a single easy-to-read type style and color and must appear on a single-color contrasting background. The print may appear in upper and lower case letters, with the lower case letters not smaller than one-third (⅓) the size of the largest letter.

(5) The word ''enhanced'' cannot be used in the product name.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55983, Nov. 3, 1995; 66 FR 40845, Aug. 6, 2001; 79 FR 79061, Dec. 31, 2014]

§ 381.118 Ingredients statement.

(a)(1) The label shall show a statement of the ingredients in the poultry product if the product is fabricated from two or more ingredients. Such ingredients shall be listed by their common or usual names in the order of their descending proportions, except as prescribed in paragraph (a)(2) of this section.

(2)(i) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided,* That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as ''Contains _____ percent or less of _____,'' or ''Less than _____ percent of _____.'' The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(ii) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with subpart P of this part and § 424.21(c) of subchapter E, and does not

exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(b) For the purpose of this paragraph, the term ''chicken meat,'' unless modified by an appropriate adjective, is construed to mean deboned white and dark meat; whereas the term ''chicken'' may include other edible parts such as skin and fat not in excess of their natural proportions, in addition to the chicken meat. If the term ''chicken meat'' is listed and the product also contains skin, giblets, or fat, it is necessary to list each such ingredient. Similar principles shall be followed in listing ingredients of poultry products processed from other kinds of poultry.

(c) The terms spice, natural flavor, natural flavoring, flavor or flavoring may be used in the following manner:

(1) The term ''spice'' means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(2) The term ''natural flavor,'' ''natural flavoring,'' ''flavor'' or ''flavoring'' means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portions of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

(i) Natural flavor, natural flavoring, flavor or flavoring as described in paragraph (c)(1) and (2) of this section, which are also colors shall be designated as ''natural flavor and coloring,'' ''natural flavoring and coloring,'' ''flavor and coloring'' or ''flavoring and coloring'' unless designated by their common or usual name.

(ii) Any ingredient not designated in paragraphs (c) (1) and (2) of this section whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock or poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

(d) On containers of frozen dinners, entrees, and pizzas, and similarly packaged products in cartons, the ingredient statement may be placed on the front riser panel: *Provided,* That the words ''see ingredients,'' followed immediately by an arrow pointing to the front riser panel, are placed on the principal display panel immediately above the location of such statement, without intervening printing or designs.

(e) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(f) Establishments may interchange the identity of two kinds of poultry (e.g., chicken and turkey, chicken meat and turkey meat) used in a product formulation without changing the product's ingredient statement or product name under the following conditions:

(1)(i) The two kinds of poultry used must comprise at least 70 percent by weight of the poultry and the poultry ingredients [e.g. giblets, skin or fat in excess of natural proportions, or mechanically separated (kind)] used; and,

(ii) Neither of the two kinds of poultry used can be less than 30 percent by weight of the total poultry and poultry ingredients used;

(2) The word ''and'' in lieu of a comma must be shown between the declaration of the two kinds of poultry

in the ingredients statement and in the product name.

[37 FR 9706, May 16, 1972, as amended at 55 FR 7294, Mar. 1, 1990; 55 FR 26422, June 28, 1990; 58 FR 38049, July 15, 1993; 59 FR 40215, Aug. 8, 1994; 63 FR 11360, Mar. 9, 1998; 76 FR 82078, Dec. 30, 2011]

§ 381.119 Declaration of artificial flavoring or coloring.

(a) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of any poultry product, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as ''Artificial Smoke Flavoring Added'' or ''Smoke Flavoring Added,'' as applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring added as an ingredient in the formula of the poultry product.

(b) Any poultry product which bears or contains any artificial flavoring other than an artificial smoke flavoring or a smoke flavoring, or bears or contains any artificial coloring shall bear a statement stating that fact on the immediate container or, if there is none, on the product.

§ 381.120 Antioxidants; chemical preservatives; and other additives.

When an antioxidant is added to a poultry product, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement showing the name of the antioxidant and the purpose for which it is added, such as ''BHA added to help protect the flavor.'' Immediate containers of poultry products packed in, bearing, or containing any chemical preservative shall bear a label stating that fact and naming the additive and the purpose of its use. Immediate containers of poultry products packed in, bearing or containing any other chemical additive shall bear a label naming the additive and the purpose of its use when required by the Administrator in specific cases. When approved proteolytic enzymes as permitted in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B of this subchapter are used in mature poultry muscle tissue, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement ''Tenderized with [approved enzyme],'' to indicate the use of such enzymes. Any other approved substance which may be used in the solution shall also be included in the statement. When approved inorganic chlorides as permitted in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B of this subchapter are used in mature poultry muscle tissue, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement, ''Tenderized with (name of approved inorganic chloride(s))'' to indicate the use of such inorganic chlorides. Any other approved substance which may be used in the solution shall also be included in the statement.

[37 FR 9706, May 16, 1972, as amended at 45 FR 58820, Sept. 5, 1980; 49 FR 18999, May 4, 1984; 64 FR 72175, Dec. 23, 1999]

§ 381.121 Quantity of contents.

(a) The label shall bear a statement of the quantity of contents in terms of weight or measures as provided in paragraph (c)(5) of this section. However, the Administrator may approve the use of labels for certain types of consumer packages which do not bear a statement of the net weight that would otherwise be required under this subparagraph: *Provided*, That the shipping container bears a statement ''Net weight to be marked on consumer packages prior to display and sale'': *And provided further*, That the total net weight of the contents of the shipping container is marked on such container: *And provided further*, That the shipping container bears a statement ''Tare weight of consumer package'' and in close proximity thereto, the actual tare weight (weight of packaging material), weighed to the nearest one-eighth ounce or less, of the individual consumer package in the shipping container. The above-specified statements may be added to approved shipping container labels upon approval by the inspector in charge.

(b) When a poultry product and a nonpoultry product are separately

wrapped and are placed in a single immediate container bearing the same name of both products, the net weight on such immediate container may be the total net weight of the products, or such immediate container may show the net weights of the poultry product and the nonpoultry product separately. Notwithstanding the other provisions of this paragraph, the label on consumer size retail packages of stuffed poultry and other stuffed poultry products must show the total net weight of the poultry product, and in close proximity thereto, a statement specifying the minimum weight of the poultry in the product.

(c)(1) The statement of net quantity of contents shall appear (except as otherwise permitted under this paragraph (c)), on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type, in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph (c). An unused tare weight, as defined in section 381.121b of this subchapter, may be printed adjacent to the statement of net quantity of contents when the product is packaged totally with impervious packaging material and is packed with a usable medium.

(2) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel, in lines generally parallel to the base: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph. The declaration may appear in more than one line.

(3) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on containers, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on containers, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenth inch in height on containers, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on containers, the principal display panel of which has an area of more than 100 but not more than 400 square inches;

(v) Not less than one-half inch in height on containers, the principal display panel of which has an area of more than 400 square inches.

(vi) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). This height standard pertains to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter ''o'' or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(4) The statement shall appear as a distinct item on the principal display panel and shall be separated, from other label information appearing to the left or right of the statement, by a space at least equal in width to twice the width of the letter ''N'' of the style of type used in the quantity of contents statement and shall be separated from other label information appearing above or below the statement by a space at least equal in height to the height of the lettering used in the statement.

(5) The terms ''net weight'' or ''net wt.'' shall be used when stating the net quantity of contents in terms of weight, and the term ''net contents'' or ''contents'' when stating the net quantity of contents in terms of fluid measure. Except as provided in § 381.128, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of

weight if the product is solid, semisolid, viscous or a mixture of solid and liquid. On packages containing less than 1 pound or 1 pint, the statement shall be expressed in ounces or fractions of a pint, respectively. On packages containing 1 pound or 1 pint or more, and less than 4 pounds or 1 gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parenthesis) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fraction of the pint or quart. For example, a declaration of three-fourths pound avoirdupois weight shall be expressed as ''Net Wt. 12 oz.''; a declaration of 1½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz. (1 lb. 8 oz.),'' ''Net Wt. 24 oz. (1½ lb.),'' or ''Net Wt. 24 oz. (1.5 lbs.).'' However, on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. The numbers may be written in provided the unit designation is printed. Paragraphs (c) (8) and (9) of this section permit certain exceptions to this paragraph for multi-unit packages, and random weight consumer size and small packages (less than ½ ounce), respectively.

(6) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in section 381.121b of this subchapter. The statement shall not include any term qualifying a unit of weight, measure, or count such as ''jumbo quart,'' ''full gallon,'' ''giant quart,'' ''when packed,'' ''minimum,'' or words of similar importance except as provided in paragraph (b) of this section.

(7) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(8) On a multiunit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as otherwise required by this paragraph (c). ''A multiunit retail package'' is a package containing two or more individually packaged units of the identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being sold individually. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph (c)(8) if the labeling of each individual unit complies with the requirements of this paragraph (c).

(9) The following exemptions from the requirements contained in this section are hereby established:

(i) Individually wrapped, random weight consumer size packages of poultry products (as specified in paragraph (c)(10) of this section) and poultry products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined in NBS handbook 133, section 3.18.2, need not bear a net weight statement when shipped from an official establishment provided a net weight shipping statement which meets the requirements of paragraph (c)(6) of this section is applied to the shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size,

dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement of random weight consumer size packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (c)(6) of this section;

(iii) Individually wrapped and labeled packages of less than ½ ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(10) As used in this section a ''random weight consumer size package'' is one of a lot, shipment or delivery of packages of the same product, with varying weights and with no fixed weight pattern.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 53 FR 28635, July 29, 1988; 55 FR 49835, Nov. 30, 1990]

§§ 381.121a–381.121e [Reserved]

§ 381.122 Identification of manufacturer, packer or distributor.

The name and address, including zip code, of the manufacturer, packer, or distributor shall be shown on the label and if only the name and address of the distributor is shown, it shall be qualified by such term as ''packed for,'' ''distributed by,'' or ''distributors.'' The name and place of business of the manufacturer, packer, or distributor may be shown on the principal display panel, on the 20-percent panel of the principal display panel reserved for required information, on the front riser panel of frozen food cartons, or on the information panel.

[37 FR 9706, May 16, 1972, as amended at 59 FR 40215, Aug. 8, 1994]

§ 381.123 Official inspection mark; official establishment number.

The immediate container of every inspected and passed poultry product shall bear:

(a) The official inspection legend; and

(b) The official establishment number of the official establishment in which the product was processed under inspection and placed as follows:

(1) Within the official inspection legend in the form required by subpart M of this part; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix ''P''; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling in the container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as ''Plant No. on Package Closure'' or ''Plant No. on Pan'', if shown in a prominent and legible manner in a size sufficient to ensure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix ''P''.

[47 FR 29515, July 7, 1982]

§ 381.124 Dietary food claims.

If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity

with regulations (21 CFR part 125) established pursuant to sections 403 and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

§ 381.125 Special handling label requirements.

(a) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: ''Keep Refrigerated,'' ''Keep Frozen,'' ''Keep Refrigerated or Frozen,'' ''Perishable—Keep Under Refrigeration,'' or such similar statement as the Administrator may approve in specific cases. The immediate containers for products that are frozen during distribution and intended to be thawed prior to or during display for sale shall bear the statement ''Shipped/Stored and Handled Frozen for Your Protection, Keep Refrigerated or Freeze.'' For all canned perishable products, the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be shown in letters one-half inch in height.

(b) Safe handling instructions shall be provided for all poultry products not processed in accordance with the provisions of § 381.150(a) or that have not undergone other processing that would render them ready-to-eat, except as exempted under paragraph (b)(4) of this section.

(1) (i) Safe handling instructions shall accompany the poultry products, specified in this paragraph (b), destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading ''Safe Handling Instructions'' which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (b)(2) and (b)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) (i) The labels of the poultry products, specified in this paragraph (b) and prepared from inspected and passed poultry, shall include the following rationale statement as part of the safe handling instructions, ''This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(ii) The labels of the poultry products, specified in this paragraph (b) and prepared pursuant to § 381.10(a) (2), (5), (6), and (7), shall include the following rationale statement as part of the safe handling instructions, ''Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Poultry products, specified in this paragraph (b), shall bear the labeling statements.

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Poultry products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (b)(1) through (b)(3) of this section.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 14540, Mar. 28, 1994; 64 FR 746, Jan. 6, 1999]

§ 381.126 Date of packing and date of processing; contents of cans.

(a) Either the immediate container or the shipping container of all poultry food products shall be plainly and permanently marked by code or otherwise with the date of packing. If calendar dating is used, it must be accompanied by an explanatory statement, as provided in § 381.129(c)(2).

(b) The immediate container for dressed poultry shall be marked with a lot number which shall be the number of the day of the year on which the poultry was slaughtered or a coded number.

(c) All canned products shall be plainly and permanently marked, by code or otherwise, on the containers, with the identity of the contents and date of canning, except that canned products packed in glass containers are not required to be marked with the date of canning if such information appears on the shipping container. If calendar dating is used, it must be accompanied by an explanatory statement, as provided in § 381.129(c)(2).

(d) If any marking is by code, the inspector in charge shall be informed as to its meaning.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 35784, Oct. 4, 1974]

§ 381.127 Wording on labels of shipping containers.

(a) Each label for use on a shipping container for inspected and passed poultry products shall bear, in distinctly legible form, the following information:

(1) The official inspection legend.

(2) The official establishment number of the official establishment in which the poultry product was inspected, either within the official inspection mark, or elsewhere on the container clearly visible and in proximity to the official inspection mark.

§ 381.128 Labels in foreign languages.

Any label to be affixed to a container of any dressed poultry or other poultry product for foreign commerce may be printed in a foreign language. However, the official inspection legend and establishment number shall appear on the label in English, but in addition, may be literally translated into such foreign language. Each such label shall be subject to the applicable provisions of §§ 381.115 to 381.141, inclusive. Deviations from the form of labeling required under the regulations may be approved by the Administrator in specific cases and such modified labeling may be used for poultry products to be exported: *Provided*, (a) That the proposed labeling accords to the specifications of the foreign purchaser, (b) that it is not in conflict with the Act or the laws of the country to which it is intended for export, and (c) that the outside of the shipping container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of the regulations shall apply.

§ 381.129 False or misleading labeling or containers.

(a) No poultry product subject to the Act shall have any false or misleading labeling or any container that is so made, formed, or filled as to be misleading. However, established trade names and other labeling and containers which are not false or misleading and which are approved by the Administrator in the regulations or in specific cases are permitted.

(b) No statement, word, picture, design, or device which is false or misleading in any particular or conveys any false impression or gives any false indication of origin, identity, or quality, shall appear on any label. For example:

(1) Official grade designations such as the letter grades A, B, and C may be used in labeling individual carcasses of poultry or containers of poultry products only if such articles have been graded by a licensed grader of the Federal or Federal-State poultry grading service and found to qualify for the indicated grade.

(2) Terms having geographical significance with reference to a particular locality may be used only when the product was produced in that locality.

(3) ''Fresh frozen'', ''quick frozen'', ''frozen fresh'', and terms of similar import apply only to ready-to-cook poultry processed in accordance with § 381.66(f)(1). Ready-to-cook poultry handled in any other manner and dressed poultry may be labeled ''frozen'' only if it is frozen in accordance with § 381.66(f)(2) under Department supervision and is in fact in a frozen state. ''Individually quick frozen (Kind)'' and terms of similar import are applicable only to poultry products that are frozen as stated on the label and whose component parts can be easily separated at time of packing.

(4) Poultry products labeled with a term quoted in any paragraph of § 381.170(b) shall comply with the specifications in the applicable paragraph. However, parts of poultry may be cut in any manner the processor desires as long as the labeling appropriately reflects the contents of the container of such poultry.

(5) The terms ''All,'' ''Pure,'' ''100%,'' and terms of similar connotation shall not be used on labels for products to identify ingredient content, unless the product is prepared solely from a single ingredient.

(6)(i) A raw poultry product whose internal temperature has ever been below 26 °F may not bear a label declaration of ''fresh.'' A raw poultry product bearing a label declaration of ''fresh'' but whose internal temperature has ever been below 26 °F is mislabeled. The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26 °F standard by 1 degree (i.e., have a temperature of 25 °F) and still be labeled ''fresh.'' The temperature of individual packages of raw poultry product outside an official establishment may deviate below the 26 °F standard by 2 degrees (i.e., have a temperature of 24 °F) and still be labeled ''fresh.'' The average temperature of poultry product lots of each specific product type must be 26 °F. Product described in this paragraph is not subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(ii) Raw poultry product whose internal temperature has ever been at or below 0°F must be labeled with the descriptive term ''frozen,'' except when such labeling duplicates or conflicts with the labeling requirements in § 381.125 of this subchapter. The word ''previously'' may be placed next to the term ''frozen'' on an optional basis. The descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it must be prominently affixed to the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Product described in this paragraph is subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(iii) Raw poultry product whose internal temperature has ever been below 26 °F, but is above 0 °F, is not required to bear any specific descriptive term. Raw poultry product whose internal temperature has ever been below 26 °F, but is above 0 °F, may bear labeling with an optional, descriptive term, provided the optional, descriptive term does not cause the raw poultry product to become misbranded. If used, an optional, descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the optional, descriptive term is affixed to the label, it must be prominently affixed on the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(iv) *Handling and relabeling of products.* (A) Except as provided under paragraph (b)(6)(iii)(C) of this section, when any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, such product may be transported in commerce to an official establishment after oral permission is obtained from the Area Supervisor of the area in which that official establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person desiring to handle the product. The transportation shall be authorized only for the purpose of the relabeling of the product. The Area Supervisor shall record the authorization and other information necessary to identify the product and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(B) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by the inspector, and if it is found that the product is not adulterated, it may be received into the establishment; but if the product is found to be adulterated, it shall at once be condemned and disposed of in accordance with § 381.95 of this subchapter. Wholesome product will be relabeled in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate.

(C) When any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, the owner may transport the product in commerce to a retail entity for relabeling in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate, or to other end users, such as hotels, restaurants or similar institutions; or, relabel the product in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate if the product is already at a retail entity. A hotel, restaurant or similar institution is not required to relabel product misbranded under this subpart; *Provided,* That the product is prepared in meals or as entrees only for sale or service directly to individual consumers at such institutions, and that the mark of inspection is removed or obliterated. Oral permission shall be obtained from the Area Officer-in-Charge of the Compliance Program for the area in which the product is located prior to such transportation or relabeling. The Area Officer-in-Charge shall record the authorization and other information necessary to identify the product, and shall furnish a copy of the authorization record upon request. Before being offered for sale at a retail entity, such product shall be relabeled.

(v) Ready-to-cook chicken may bear the claim ''air chilled'' or ''air chilling'' on its label only if the product was chilled under a process that meets the definition of air chilling in § 381.66(e).

(c) A calendar date may be shown on labeling when declared in accordance with the provisions of this paragraph:

(1) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(2) Immediately adjacent to the calendar date will be a phrase explaining the meaning of such date in terms of ''packing'' date, ''sell by'' date, or ''use before'' date, with or without a further qualifying phrase, e.g., ''For Maximum Freshness'' or ''For Best Quality.''

(d) When sodium alginate, calcium carbonate, lactic acid, and calcium lactate are used together in a dry binding matrix in ground or formed poultry products, as permitted in § 424.21(c) of subchapter E, there shall appear on the label contiguous to the product name a statement to indicate the use of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.

(e) When transglutaminase enzyme is used to bind pieces of poultry to form a cut of poultry, or to reform a piece of poultry from a multiple cuts of poultry, there shall appear on the label, as

part of the product name, a statement that indicates that the product has been ''formed'' or ''reformed,'' in addition to other preparation steps, e.g., ''Formed Turkey Thigh Roast'' or ''Reformed and Shaped Chicken Breast.''

(f) A country of origin statement on the label of any poultry product ''covered commodity'' as defined in 7 CFR part 65, subpart A, that is to be sold by a ''retailer,'' as defined in 7 CFR 65.240, must comply with the requirements in 7 CFR 65.300 and 65.400.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 42339, Dec. 5, 1974; 55 FR 5977, Feb. 21, 1990; 60 FR 44412, Aug. 25, 1995; 61 FR 66200, Dec. 17, 1996; 61 FR 68821, Dec. 30, 1996; 66 FR 54916, Oct. 31, 2001; 73 FR 50703, Aug. 28, 2008; 76 FR 82078, Dec. 30, 2011; 78 FR 66838, Nov. 7, 2013; 79 FR 49637, Aug. 21, 2014]

§ 381.130 False or misleading labeling or containers; orders to withhold from use.

If the Administrator has reason to believe that any marking or other labeling or the size or form of any container in use or proposed for use with respect to any article subject to the Act is false or misleading in any particular, he may direct that the use of the article be withheld unless it is modified in such manner as the Administrator may prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Administrator, he may request a hearing, but the use of the labeling or container shall, if the Administrator so directs, be withheld pending hearing and final determination by the Secretary in accordance with applicable rules of practice. Any such determination with respect to the matter by the Secretary shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the Circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

§ 381.131 Preparation of labeling or other devices bearing official inspection marks without advance approval prohibited; exceptions.

(a) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label, or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph do not apply to marking devices containing the official inspection legend shown in Figure 5 of § 381.102.

(b) No brand manufacturer or other person shall cast or otherwise make, without an official certificate issued in quadruplicate by a Program employee, a marking device containing the official inspection legend shown in Figure 5 of § 381.102 or any simulation of that legend.

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the marking device manufacturer.

(3) The manufacturer of the marking devices shall engrave or otherwise mark each marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer

the number of each marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such marking device that does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0015)

[50 FR 21423, May 24, 1985]

§§ 381.132–381.133 [Reserved]

§ 381.134 Requirement of formulas.

Copies of each label submitted for approval, shall when the Administrator requires in any specific case, be accompanied by a statement showing, by their common or usual names, the kinds and percentages of the ingredients comprising the poultry product and by a statement indicating the method or preparation of the product with respect to which the label is to be used. Approximate percentages may be given in cases where the percentages of ingredients may vary from time to time, if the limits of variation are stated.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 45196, Sept. 1, 1994. Redesignated at 60 FR 67457, Dec. 29, 1995]

§ 381.136 Affixing of official identification.

(a) No official inspection legend or any abbreviation or other simulation thereof may be affixed to or placed on or caused to be affixed to or placed on any poultry product or container thereof, except by an inspector or under the supervision of an inspector or other person authorized by the Administrator, and no container bearing any such legend shall be filled except under such supervision.

(b) No official inspection legend shall be used on any poultry product or other article which does not qualify for such mark under the regulations.

§ 381.137 Evidence of labeling and devices approval.

No inspector shall authorize the use of any device bearing any official inspection legend unless he or she has on file evidence that such device has been approved in accordance with the provisions of this subpart.

[60 FR 67458, Dec. 29, 1995]

§ 381.138 Unauthorized use or disposition of approved labeling or devices.

(a) Labeling and devices approved for use pursuant to § 381.115 shall be used only for the purpose for which approved, and shall not be disposed of from the official establishment for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labeling or devices bearing official inspection marks is prohibited and may result in cancellation of the approval.

(b) Labeling and containers bearing any official inspection marks, with or without the official establishment number, may be transported from one official establishment to any other official establishment, only if such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. Approved labeling and containers may be moved without restriction under this part between official establishments operated by the same person if such labeling and containers are approved for use at all such establishments. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subpart.

§ 381.139 Removal of official identifications.

(a) Every person who receives any poultry product in containers which bear any official inspection legend shall remove or deface such legend or

destroy the containers upon removal of such articles from the containers.

(b) No person shall alter, detach, deface, or destroy any official identifications prescribed in subpart M that were applied pursuant to the regulations, unless he is authorized to do so by an inspector or this section; and no person shall fail to use any such official identification when required by this part.

§ 381.140 Relabeling poultry products.

When it is claimed by the operator of an official establishment that some of its labeled poultry product, which has been transported to a location other than an official establishment, is in need of relabeling because the labeling has become mutilated or damaged, or for some other reason needs relabeling, the requests for relabeling the poultry product shall be sent to the Administrator and accompanied with a statement of the reasons therefor and the quantity of labeling required. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with official labels shall be done under the supervision of an inspector pursuant to the regulations in part 362 of this chapter. The establishment shall reimburse the Inspection Service for any cost involved in supervising the relabeling of such product as provided in said regulations.

§§ 381.141–381.143 [Reserved]

§ 381.144 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for the intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will monitor the use of packaging materials in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information to designated Department officials as needed to verify the basis

for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request—a minimum of 30 days—any applicable guaranty shall cease to be effective and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(e) The Administrator may disapprove for use in official establishments packaging materials whose use cannot be confirmed as complying with the FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2236, Jan. 19, 1984]

Subpart O—Entry of Articles Into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

(a) No poultry product (including poultry broth for use in any poultry product in any official establishment) may be brought into any official establishment unless it has been processed in the United States only in an official establishment or imported from a foreign country listed in § 381.196(b), and inspected and passed, in accordance with the regulations; and unless the container of such product is marked so as to identify the product as so inspected and passed, in accordance with § 381.115 or § 381.205, except that poultry products inspected and passed and identified as such under the laws of an ''at least equal'' State or territory listed in § 381.187 may be brought into any official establishment solely for storage and distribution therefrom without repackaging, relabeling, or processing in such establishment. No carcass, part thereof, meat or meat food product of cattle, sheep, swine, goats, or equines may be brought into an official establishment unless it has been prepared in the United States only in an official meat packing establishment, or imported, and inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (Subchapter A of this chapter) and is properly marked as so inspected and passed; or has been inspected and passed and is identified as such in accordance with the requirements of the law and regulations of a State not designated in § 331.2 of this chapter; or is present in the official establishment by reason of an exemption allowed in the Federal Meat Inspection Act and the regulations under such Act

(Subchapter A of this chapter) or the law and regulations of a State not so designated. However, such exempted articles may enter only under conditions approved by the Administrator in specific cases, including but not limited to, complete separation of inspected poultry products and processing and other operations with respect thereto from the exempted articles and operations with respect thereto, complete cleanup of facilities and equipment between processing of inspected poultry products and the exempted articles and no commingling of inspected and exempted articles in receiving, holding or storage areas.

(b) All poultry products and all carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines which enter any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment. All poultry products, and all carcasses, parts thereof, meat and meat food products of such animals, which are processed or otherwise handled at any official establishment shall be subject to examination by an inspector at the official establishment in such manner and at such times as may be deemed necessary by the inspector in charge to assure compliance with the regulations. Upon such examination, if any such article or portion thereof is found to be adulterated, such article or portion shall, in the case of poultry products, be condemned and disposed of as prescribed in § 381.95, unless by reprocessing they may be made not adulterated, and shall, in the case of such other articles be disposed of according to applicable law.

Such examination may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The inspector in charge shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.[1]

[1] Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisor. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved.

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing poultry product who has a total plant quality control system or plan for controlling such products, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of a small establishment which does not have full-time quality control personnel, information

indicating the nature of the duties and responsibilities of the person who will also be responsible for the quality control system.

(3) A list identifying those subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action—ranging from the least to most severe: *Provided*, That subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d)–(e) [Reserved]

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section may only use, as a part of any label, the following logo.

(g) *Termination of Quality Control Systems.* (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or a quality control system for irradiation facilities may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded poultry product is found by the Adminstrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict, The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator

within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(4) If approval of a quality control system for irradiation facilities, as specified in section 381.149 of this subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

(h)(1) *Operating Schedule Under Total Plant Quality Control.* An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permissions will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in § 381.145(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspectiom services at the discretion of the circuit supervisor and charged for such services.

(i) To ensure the safe use of preparations used in poultry scald water, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B or 9 CFR Chapter III, Subchapter A or Subchapter E.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0015)

[37 FR 9706, May 16, 1972, as amended at 45 FR 54323, Aug. 15, 1980; 46 FR 48904, Oct. 5, 1981; 50 FR 6, Jan. 2, 1985; 51 FR 32304, Sept. 11, 1986; 57 FR 43598, Sept. 21, 1992; 62 FR 45026, Aug. 25, 1997; 62 FR 54759, Oct. 22, 1997; 64 FR 72175, Dec. 23, 1999; 65 FR 34390, May 30, 2000; 78 FR 66838, Nov. 7, 2013]

§ 381.146 Sampling at official establishments.

Inspectors may take, without cost to the Department, such samples as are necessary of any poultry product, or other article for use as an ingredient of any poultry product, at any official establishment to determine whether it complies with the requirements of the regulations.

§ 381.148 Processing and handling requirements for frozen poultry products.

Procedures with respect to processing of frozen ready-to-heat-and-eat poultry products or stuffed ready-to-roast poultry shall be in accordance with sound operating practices and carried out in a manner which will assure freedom from adulteration of the products. Products to be frozen shall be moved into the freezer promptly under such supervision by an inspector as is necessary to assure preservation of the products by prompt and efficient freezing. Adequate freezing facilities shall be provided within the official establishment where products to be frozen

are prepared, except that, upon written request, and under such conditions as may be prescribed by the Administrator in specific cases, such products may be moved from the official establishment prior to freezing: *Provided*, That the official establishment and freezer are so located and the necessary arrangements are made so that the Inspection Service will have access to the freezing room and adequate opportunity to determine that the products are being properly handled and frozen.

§ 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.

(a) Fully cooked poultry products must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality*. A 7-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) *Stabilization*. There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than a 1 $\log_{10}$ multiplication of *Clostridium perfringens* within the product.

(b) Partially cooked poultry breakfast strips must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section. Labeling for these products must comply with § 381.125. In addition, the statement ''Partially Cooked: For Safety, Cook Until Well Done'' must appear on the principal display panel in letters no smaller than ½ the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 381.1(b). Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(d) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

[64 FR 746, Jan. 6, 1999]

§ 381.151 Adulteration of product by polluted water; procedure for handling.

(a) In the event there is polluted water (including but not limited to flood water) in an official establishment, all poultry products and ingredients for use in the preparation of such products that have been rendered adulterated by the water shall be condemned.

(b) After the polluted water has receded from an official establishment, all walls, ceilings, posts, and floors of the rooms and compartments involved, including the equipment therein, shall, under the supervision of an inspector, be cleaned thoroughly by the official establishment personnel. An adequate supply of hot water under pressure is essential to make such cleaning effective. After cleaning a solution of sodium hypochlorite containing approximately one-half of 1 percent available chlorine (5,000 p/m) or other equivalent disinfectant approved by the Administrator[1] shall be applied to the surface of the rooms and equipment and rinsed with potable water before use.

[1] A list of approved disinfectants is available upon request to Scientific Services, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(c) Hermetically sealed containers of poultry product which have been contaminated by polluted water shall be examined promptly by the official establishment under supervision of an inspector and rehandled as follows:

(1) Separate and condemn all poultry products in damaged or extensively rusted containers.

(2) Remove paper labels and wash the remaining containers in warm soapy water, using a brush where necessary to remove rust or other foreign material. Disinfect these containers by either of the following methods:

(i) Immerse in a solution of sodium hypochlorite containing not less than 100 p/m of available chlorine or other equivalent disinfectant approved by the Administrator,[1] rinse in potable water, and dry thoroughly; or

(ii) Immerse in 212 °F. water, bring temperature of the water back to 212 °F. and maintain the temperature at 212 °F. for 5 minutes, then remove containers from water and cool them to 95 °F. and dry thoroughly.

(3) After handling as described in paragraph (c)(2) of this section, the containers may be relacquered, if necessary, and then relabeled with approved labels applicable to the product therein.

(4) The identity of the canned poultry product shall be maintained throughout all stages of the rehandling operations, to insure correct labeling of containers.

[38 FR 34456, Dec. 14, 1973]

§ 381.152 Preparation in an official establishment of articles not for human food.

(a) *Requirements applicable when prepared in an edible products department.* When an article (including, but not being limited to, animal food) that is not for use as human food is prepared in any room or compartment, in an official establishment where poultry products are prepared or handled (such room or compartment being herein referred to as an ''edible products department''), sufficient space and equipment shall be provided to assure that the preparation of the article in no way interferes with the preparation or other handling of the poultry products. Where necessary, separate equipment shall be provided for the preparation of the article. To assure the maintenance of the requisite sanitary conditions in the edible products department, the operations incident to the preparation of the article shall be subject to the same sanitary requirements as apply to the handling of poultry products in the edible products department. Preparation of the article shall be limited to those hours during which the official establishment operates under the supervision of an inspector. The ingredients used in the preparation of the article shall, unless otherwise approved by the Administrator in specific cases, be such as may be used in the preparation of a poultry product. The article may be stored in, and distributed from, the edible products department if the article is properly identified.

(b) *Requirements applicable when prepared in an inedible products department.* When an article (including, but not being limited to, animal food) that is not for use as human food, is prepared in any part of an official establishment other than an edible products department (such part of the establishment being herein referred to as the ''inedible products department''), the area in which such article is prepared shall be distinctly separated from all edible products departments. Poultry products and inedible products may be brought from any edible products department into any inedible products department, but no poultry product or inedible product may be brought from an inedible products department into an edible products department except that any such articles as are in sealed containers or are handled under conditions prescribed or approved by the Administrator in specific cases may be brought into an edible products department. Diseased carcasses or diseased parts of any carcass shall not be used in the preparation of any animal food unless they have been treated in the manner prescribed in § 381.95(a). Trucks or containers used for the transportation of poultry products or inedible products into an inedible products department shall be cleaned before being returned to or brought into an edible products department. Sufficient space shall be allotted and adequate equipment and facilities provided so that the

preparation of the article does not interfere with the preparation of poultry products or the maintenance of the requisite sanitary conditions in the official establishment. The preparation of any such article shall be subject to supervision by an inspector.

(c) *Containers to be labeled.* The immediate container of any such article that is prepared in an official establishment shall be conspicuously labeled so as to distinguish it from human food. Such articles are also subject to the requirements under the Federal Food, Drug, and Cosmetic Act.

§ 381.153 [Reserved]

Subpart P—Definitions and Standards of Identity or Composition

§ 381.155 General.

(a) *Authorization to establish specifications.* (1) The Administrator is authorized to establish specifications or definitions and standards of identity or composition, covering the principal constituents of any poultry product with respect to which a specified name of the product or other labeling terminology may be used, whenever he determines such action is necessary to prevent sale of the product under false or misleading labeling. Further, the Administrator is authorized to prescribe definitions and standards of identity or composition for poultry products whenever he determines such action is otherwise necessary for the protection of the public. The requirements of this subpart are hereby found to be necessary for these purposes and standards are hereby established as set forth in this subpart.

(2) Where cooked poultry meat is specified in this subpart as an ingredient of poultry products, this means poultry meat derived from poultry processed, cooked, and cooled in a manner approved by the Administrator in specific cases without use of liquid or moisture in direct contact with the poultry meat following the cooking and cooling of the poultry.

(3) If, following cooking and cooling of poultry meat to be used in poultry products, liquid or moisture is used in direct contact with such poultry meat and the percentage of solids, excluding salt, in the poultry meat is found to be below 34 percent when such poultry meat is tested by acceptable methods, the percentage of poultry meat required by this section for any poultry product shall be increased in proportion to the deficiency, or the meat shall be so processed as to raise the solids content, excluding salt, to 34 percent. The official establishment shall furnish adequate facilities for such testing.

(b) Any binder or antimicrobial agent that has been found to be safe and suitable by the Food and Drug Administration and the Food Safety and Inspection Service may be used in the production of poultry products with standards of identity in this part, where the product standards and applicable Federal regulations already permit the use of these types of ingredients.

[37 FR 9706, May 16, 1972, as amended at 68 FR 22578, Apr. 29, 2003]

§ 381.156 Poultry meat content standards for certain poultry products.

Poultry products with labeling terminology as set forth in Table I shall comply with the specifications for percent light meat and percent dark meat set forth in said table.

TABLE I

Label terminology	Percent light meat	Percent dark meat
Natural proportions	50–65	50–35.
Light or white meat	100	0.
Dark meat	0	100.
Light and dark meat	51–65	49–35.
Dark and light meat	35–49	65–51.
Mostly white meat	66 or more	34 or less.
Mostly dark meat	34 or less	66 or more.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

§ 381.157 Canned boned poultry and baby or geriatric food.

(a) Canned boned poultry shall, unless otherwise specified in this section, be prepared from cooked deboned poultry meat and may contain skin and fat not in excess of natural whole carcass proportions. Gelatin, stabilizers, or similar solidifying or emulsifying agents shall not be added to product labeled ''Boned (Kind)—Solid Pack,'' but

may be added in quantities not in excess of a total of 0.5 percent of the total ingredients in the preparation of other canned boned poultry products and in such cases the common name of the substance shall be included in the name of the product, e.g., ''Boned Chicken with Broth—Gelatin Added.''

(b) Canned boned poultry, except poultry within paragraph (c) of this section, shall meet the requirements set forth in Table II. The percentages in Table II shall be calculated on the basis of the total ingredients used in the preparation of the product.

(c) Canned boned poultry with natural juices (Boned (Kind) with natural juices) shall be prepared from either raw boned poultry or a mixture of raw boned poultry and cooked boned poultry and shall have no liquid added during the preparation of the product.

(d) Canned shredded poultry (Shredded Kind), consists of poultry meat reduced to a shredded appearance, from the kind of poultry indicated, with meat, skin, and fat not in excess of the natural whole carcass proportions. Canned shredded poultry from specific parts may include skin or fat in excess of the proportions normally found on a whole carcass, but not in excess of the proportions of skin and fat normal to the particular part or parts; and such product shall be labeled in accordance with § 381.117(d).

(e) Canned boned poultry shall be prepared as set forth in Table II, items 1, 2, 3, or 4, whichever is applicable.

TABLE II

Product name	Minimum percent cooked, deboned poultry meat of kind indicated, with skin, fat, and seasoning	Maximum percent liquid that may be added [1]
1. Boned (Kind)—solid pack	95	5
2. Boned (Kind)	90	10
3. Boned (Kind) with broth [2]	80	20
4. Boned (Kind) (____) percent broth [2 3]	50	50

[1] Liquid may be in the form of, but is not limited to, broth or extractives.

[2] Alternatively, product may be prepared from raw boned poultry in combination with cooked boned poultry so long as the product complies with the specified standard.

[3] Total amount of liquid added shall be included in the name of the product; e.g., "Boned Chicken with 25 percent broth."

(f) Poultry products intended for infant or geriatric use and represented as having a ''high meat'' content shall contain not less than 18.75 percent cooked, deboned poultry meat of the kind indicated, with seasoning.

TABLE IIA

Product name	Minimum percent cooked, deboned, poultry meat of kind indicated, with seasoning	Maximum percent liquid that may be added [1]
1. Strained or chopped (Kind) with broth [2 3]	43	57
2. High meat dinner [3]	18.75	

[1] Liquid may be in the form of, but not limited to, broth or extractives.

[2] Alternatively, product may be prepared from raw boned poultry meat in combination with cooked bone poultry meat so long as the product complies with the specified standard.

[3] Label must indicate in some manner that product is for infant or geriatric servings.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

§ 381.158 Poultry dinners (frozen) and pies.

Poultry dinners (frozen) and pies shall meet the requirements set forth in Table III of this section and the percentage or weight specified therein shall be calculated on the basis of total ingredients used in the preparation of the poultry product.

TABLE III

	Minimum cooked deboned poultry meat of kind indicated		Minimum raw deboned poultry meat of kind indicated	
	Percent	Weight	Percent	Weight
(Kind) Pies	14	or 1⅛ oz. per 8-oz. pie [1]	25	or 2 oz. per 8-oz. pie. [1]
(Kind) Dinners	18	or 2 oz. [2 3]		

[1] 14 percent or 1⅛ oz., whichever is greater; or 25 percent or 2 oz., whichever is greater.

[2] Excluding weight of appetizers, desserts, etc.

[3] 18 percent or 2 oz., whichever is greater. A minimum of 45 percent, or 5 ounces per dinner, whichever is greater, of cooked poultry including bone and breading may be used in lieu of minimum 18 percent or 2 ounces of cooked deboned poultry meat and the cooked poultry including bone and breading shall not contain more than 30 percent breading.

§ 381.159 Poultry rolls.

(a) Binders or extenders may be added in accordance with a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter

I, Subchapter A or Subchapter B. In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders in poultry rolls: transglutaminase enzyme at up to 65 ppm. When binding agents are added in excess of 3 percent for cooked rolls and 2 percent for raw rolls, the common name of the agent or the term ''Binders Added'' shall be included in the name of the product; e.g., ''Turkey Roll-Gelatin Added.''

(b) With respect to heat processed rolls, 2 percent or less liquid based on the weight of the finished product without liquid may remain with or be returned to product labeled as ''(Kind) Roll.''

(c) Heat processed rolls which have more than 2 percent liquid remaining with or returned to the product shall be labeled as ''(Kind) Roll with Natural Juices.'' If more than 2 percent of any liquid other than natural cookout juices is added, the product must be labeled to indicate that fact; e.g., ''Turkey Roll with Broth.'' Liquid shall not be returned or added to product within this paragraph graph in excess of the amount normally cooked out during preparation.

[37 FR 9706, May 16, 1972, as amended at 55 FR 34684, Aug. 24, 1990; 66 FR 54916, Oct. 31, 2001]

§ 381.160 (Kind) burgers; (Kind) patties.

Such product consists of 100 percent poultry of the kind indicated, with skin and fat not in excess of natural proportions. Product containing fillers or binders shall be named ''(Kind) Patties.''

§ 381.161 "(Kind) A La Kiev."

Such product consists of poultry meat of the kind indicated, stuffed with butter which may be seasoned and the product may be wrapped in sufficient skin to cover the meat. It may be dipped in batter, fried, and frozen.

§ 381.162 "(Kind) steak or fillet."

Such product consists of a boneless slice or strip of poultry meat of the kind indicated.

§ 381.163 "(Kind) baked" or "(Kind) roasted."

Such product consists of ready-to-cook poultry of the kind indicated, that has been cooked in dry source heat, e.g., oven roasted or oven baked.

§ 381.164 "(Kind) barbecued."

Such product consists of ready-to-cook poultry of the kind indicated, that has been cooked in dry heat and basted with a seasoned sauce.

§ 381.165 "(Kind) barbecued prepared with moist heat."

Such product consists of ready-to-cook poultry of the kind indicated that has been cooked by the action of moist heat in a barbecue sauce.

§ 381.166 Breaded products.

''Breaded'' is a term applicable to any poultry product which is coated with breading or a batter and breading in an amount not to exceed 30 percent of the weight of the finished breaded product.

§ 381.167 Other poultry dishes and specialty items.

Poultry dishes and specialty items listed in Table IV of this paragraph shall meet the requirements set forth in said table, irrespective of the type of packaging, and the percentages in Table IV shall be calculated on a ready-to-serve basis, except that soup bases in institutional packs which are prepared for sale to institutional users shall have a minimum of 15 percent cooked deboned poultry meat based on the weight of the soup base product.

TABLE IV

Product name [1]	Minimum percent cooked deboned poultry meat of kind indicated	Minimum percent cooked poultry of kind indicated, indicating bone
(Kind) Ravioli	2	
(Kind) Soup	2	
Chop Suey with (Kind)	2	
(Kind) Chop Suey	4	
(Kind) Chow Mein without noodles	4	
(Kind) Tamales	6	
Noodles or Dumplings with (Kind) [2]	6	
(Kind) Stew	12	
(Kind) Fricassee of Wings		40

TABLE IV—Continued

Product name [1]	Minimum percent cooked deboned poultry meat of kind indicated	Minimum percent cooked poultry of kind indicated, indicating bone
(Kind) Noodles or Dumplings [2] ..	15	30
(Kind) with Vegetables	15	
Gravy with sliced (Kind)	15	
(Kind) Tetrazzini	15	
(Kind) chili with beans	17	
Creamed (Kind)	20	
(Kind) Cacciatore	20	40
(Kind) Fricassee	20	40
(Kind) A-La-King	20	
(Kind) croquettes	25	
Slice (Kind) with Gravy and Dressing	25	
(Kind) Salad [3]	25	
(Kind) chili	28	
(Kind) Hash	30	
Sliced (Kind) with Gravy	35	
Minced (Kind) Barbecue	40	

[1] The product name may contain other appropriate descriptive terms such as ''noodle''; e.g., ''Chicken Noodle Soup.''

[2] This standard also applies to products named (Kind) with rice or similar starches.

[3] The 25 percent-standard listed includes poultry meat plus proportions of skin and fat natural to the poultry used.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

§ 381.168 Maximum percent of skin in certain poultry products.

The poultry products listed in Table V shall have not more than the percent of skin specified in the table, when raw and when cooked.

TABLE V

Product name	Percent skin	
	Raw	Cooked
Boneless Turkey Breast or Boneless Turkey Breast Roll	14	
Boneless Turkey Thigh or Boneless Turkey Thigh Roll	8	
Boneless Turkey or Turkey Roll	15	
Boneless Chicken Breast or Boneless Chicken Breast Roll	18	20
Boneless Chicken or Chicken Roll	20	25

§ 381.169 [Reserved]

§ 381.170 Standards for kinds and classes, and for cuts of raw poultry.

(a) The following standards specify the various classes of the specified kinds of poultry and the requirements for each class:

(1) *Chickens*—(i) *Rock Cornish game hen or Cornish game hen.* A ''Rock Cornish game hen'' or ''Cornish game hen'' is a young, immature chicken (less than 5 weeks of age), of either sex, with a ready-to-cook carcass weight of not more than 2 pounds.

(ii) *Broiler or fryer.* A ''broiler'' or ''fryer'' is a young chicken (less than 10 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and flexible breastbone cartilage.

(iii) *Roaster or roasting chicken.* A ''roaster'' or ''roasting chicken'' is a young chicken (less than 12 weeks of age), of either sex, with a ready-to-cook carcass weight of 5.5 pounds or more, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that is somewhat less flexible than that of a broiler or fryer.

(iv) *Capon.* A ''capon'' is a surgically neutered male chicken (less than 4 months of age) that is tender-meated with soft, pliable, smooth-textured skin.

(v) *Hen, fowl, baking chicken, or stewing chicken.* A ''hen,'' ''fowl,'' ''baking chicken,'' or ''stewing chicken'' is an adult female chicken (more than 10 months of age) with meat less tender than that of a roaster or roasting chicken and a nonflexible breastbone tip.

(vi) *Cock or rooster.* A ''cock'' or ''rooster'' is an adult male chicken with coarse skin, toughened and darkened meat, and a nonflexible breastbone tip.

(2) *Turkeys*—(i) *Fryer-roaster turkey.* A ''fryer-roaster turkey'' is an immature turkey (less than 12 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin, and flexible breastbone cartilage.

(ii) *Young turkey.* A ''young turkey'' is a turkey (less than 8 months of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that is less flexible than that of a fryer-roaster turkey.

(iii) *Yearling turkey.* A ''yearling turkey'' is a turkey (less than 15 months of age), of either sex, that is reasonably

tender-meated with reasonably smooth-textured skin.

(iv) *Mature or old (hen or tom) turkey.* A ''mature turkey'' or ''old turkey'' is an adult turkey (more than 15 months of age), of either sex, with coarse skin and toughened flesh. Sex designation is optional.

(3) *Ducks*—(i) *Duckling.* A ''duckling'' is a young duck (less than 8 weeks of age), of either sex, that is tender-meated and has a soft bill and soft windpipe.

(ii) *Roaster duck.* A ''roaster duck'' is a young duck (less than 16 weeks of age), of either sex, that is tender-meated and has a bill that is not completely hardened and a windpipe that is easily dented.

(iii) *Mature duck or old duck.* A ''mature duck'' or an ''old duck'' is an adult duck (more than 6 months of age), of either sex, with toughened flesh, a hardened bill, and a hardened windpipe.

(4) *Geese*—(i) *Young goose.* A ''young goose'' is an immature goose, of either sex, that is tender-meated and has a windpipe that is easily dented.

(ii) *Mature goose or old goose.* A ''mature goose'' or ''old goose'' is an adult goose, of either sex, that has toughened flesh and a hardened windpipe.

(5) *Guineas*—(i) *Young guinea.* A ''young guinea'' is an immature guinea, of either sex, that is tender-meated and has a flexible breastbone cartilage.

(ii) *Mature guinea or old guinea.* A ''mature guinea'' or ''old guinea'' is an adult guinea, of either sex, that has toughened flesh and a non-flexible breastbone.

(b) The following standards specify the requirements for the specified cuts of poultry:

(1) ''Breasts'' shall be separated from the back at the shoulder joint and by a cut running backward and downward from that point along the junction of the vertebral and sternal ribs. The ribs may be removed from the breasts, and the breasts may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without affecting the appropriateness of the labeling as e.g., ''chicken breasts.'' Neck skin shall not be included with the breasts, except that ''turkey breasts'' may include neck skin up to the whisker.

(2) ''Breasts with ribs'' shall be separated from the back at the junction of the vertebral ribs and back. Breasts with ribs may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without affecting the appropriateness of the labeling as ''breasts with ribs.'' Neck skin shall not be included, except that ''turkey breasts with ribs'' may include neck skin up to the whisker.

(3) ''Wishbones'' (Pulley Bones), with covering muscle and skin tissue, shall be severed from the breast approximately halfway between the end of the wishbone (hypocledium) and front point of the breastbone (cranial process of the sternal crest) to a point where the wishbone joins the shoulder. Neck skin shall not be included with the wishbone.

(4) ''Drumsticks'' shall be separated from the thigh by a cut through the knee joint (femorotibial and patellar joint) and from the hock joint (tarsal joint).

(5) ''Thighs'' shall be disjointed at the hip joint and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(6) ''(Kind) legs'' shall be the poultry product which includes the thigh and the drumstick, i.e., the whole leg, and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(7) ''Wings'' shall include the entire wing with all muscle and skin tissue intact, except that the wingtip may be removed.

(8) ''Backs'' shall include the pelvic bones and all the vertebrae posterior to the shoulder joint. The meat shall not be peeled from the pelvic bones. The vertebral ribs and/or scapula may be removed or included without affecting the appropriateness of the name. Skin shall be substantially intact.

(9) ''Stripped backs'' shall include the vertebrae from the shoulder joint to the tail, and include the pelvic bones. The meat may be stripped off of the pelvic bones.

(10) ''Necks'', with or without neck skin, shall be separated from the carcass at the shoulder joint.

(11) ''Halves'' are prepared by making a full-length back and breast split of an eviscerated poultry carcass so as to produce approximately equal right and left sides.

(12) ''Quarters'' consist of the entire eviscerated poultry carcass, which has been cut into four equal parts, but excluding the neck.

(13) ''Breast quarter'' consists of half a breast with the wing and a portion of the back attached.

(14) ''Breast quarter without wing'' consists of a front quarter of a poultry carcass, from which the wing has been removed.

(15) ''Leg quarter'' consists of a poultry thigh and drumstick, with a portion of the back attached.

(16) ''Thigh with back portion'' consists of a poultry thigh with back portion attached.

(17) ''Legs with pelvic bone'' consists of a poultry leg with adhering meat and skin and pelvic bone.

(18) ''Wing drummette'' consists of the humerus of a poultry wing with adhering skin and meat attached.

(19) ''Wing portion'' consists of a poultry wing except that the drummette has been removed.

(20) ''Cut-up Poultry'' is any cut-up or disjointed portion of poultry or any edible part thereof, as described in this section.

(21) ''Giblets'' consist of approximately equal numbers of hearts, gizzards, and livers, as determined on a count basis.

(22) ''Major portions'' of eviscerated poultry carcasses are either carcasses from which parts may be missing, or the front or rear portions of transversely-split carcasses.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 63 FR 48960, Sept. 11, 1998; 76 FR 68064, Nov. 3, 2011; 81 FR 21709, Apr. 13, 2016]

§ 381.171 Definition and standard for "Turkey Ham."

(a) ''Turkey Ham'' shall be fabricated from boneless, turkey thigh meat with skin and the surface fat attached to the skin removed. The thighs shall be that cut of poultry described in § 381.170(b)(5) of this part.

(b) The product may or may not be smoked, and shall be cured using one or more of the approved curing agents as provided in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. The product may also contain cure accelerators, phosphates, and flavoring agents as provided in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B; common salt, sugars, spices, spice extractives, dehydrated garlic, and dehydrated onions; and water for purpose of dissolving and dispersing the substances specified above.

(c) The cooked finished product weight shall be no more than the original weight of the turkey thigh meat used prior to curing.

(d) The product name on the label shall show the word ''Turkey'' in the same size, style, color, and with the same background as the word ''Ham'' and shall precede and be adjacent to it.

(e) The product name shall be qualified with the statement ''Cured Turkey Thigh Meat.'' The qualifying statement shall be contiguous to the product name, without intervening type or designs, shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

(f) If the product is fabricated from pieces of turkey thigh meat that result from the cutting through the muscle (as opposed the whole thighs intact or

whole thighs with some incidental separation of muscle tissue during removal of the bone), the product name shall be further qualified by a descriptive statement. The product name of product fabricated from such pieces of turkey thigh meat equivalent in size to a one-half inch cube or greater shall be further qualified to specify that the product is ''Chunked and Formed.'' The product name of product fabricated from such pieces of turkey thigh meat smaller than the equivalent of a one-half inch cube shall be further qualified to specify that the product is ''Ground and Formed'' or ''Chopped and Formed'' as appropriate. The qualifying statement shall immediately follow and be contiguous to the statement required in paragraph (e) of this section, and shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

[44 FR 51190, Aug. 31, 1979; 64 FR 72175, Dec. 23, 1999]

§ 381.172 Requirements for substitute standardized poultry products named by use of an expressed nutrient content claim and a standardized term.

(a) *Description.* The poultry products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 381.413(d), for a standardized product defined in this subpart and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in this subpart. The expressed nutrient content claim shall comply with the requirements of § 381.413 and with the requirements in subpart Y of this part which define the particular nutrient content claim that is used. The poultry product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the poultry product shall be similar to those of the standardized poultry product produced under subpart P of this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in subpart P of this part, the label shall include a statement in accordance with § 381.413(d)(1) and (2) of this part, that informs the consumer of such differences (*e.g.*, if appropriate, ''not recommended for frozen storage'' or ''not suitable for roller grilling''). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients used in substitute products.* (1) Ingredients used in the product shall be those ingredients provided for in the standard as defined in subpart P of this part, except that safe and suitable ingredients permitted for use in poultry products as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in subpart P of this part for which it is a substitute.

(2) An ingredient that is specifically required by the standard prescribed in subpart P of this part shall not be replaced or exchanged with a similar ingredient from another source, for example, extruded turnips shall not replace noodles in poultry with noodles.

(3) An ingredient that is specifically prohibited from use in any poultry product by subpart P of this part shall not be added to the substitute poultry product under this section.

(4) Unless otherwise specified in this part, a substitute poultry product must meet all other requirements of the applicable standards of identity or composition.

(5) Water and fat-replacers (*e.g.*, binders), in combination, may be added to replace fat in accordance with paragraph (c) of this section.

(6) Textured vegetable protein may be used by itself or in combination with other binders and water as a fat replacer in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute poultry product that complies with this section is the appropriate expressed nutrient content claim and the applicable standardized term.

(e) *Label declaration.* (1) Each of the ingredients used in the substitute poultry product shall be declared on the label as required by this section and subpart N of this part.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in subpart P of this part, shall be identified as such with an asterisk in the ingredients statement. The statement ''*Ingredients not in regular _____'' (the blank shall be filled in with the name of the traditional standardized product) or ''**Ingredients in excess of amounts permitted in regular _____'' (the blank shall be filled in with the name of the traditional standardized product), or both, as appropriate, shall immediately follow the ingredients statement in the same type and size.

[70 FR 33818, June 10, 2005]

§ 381.173 Mechanically Separated (Kind of Poultry).

(a) ''Mechanically Separated (Kind of Poultry)'' is any product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses that has a paste-like form and consistency, that may or may not contain skin with attached fat and meeting the other provisions of this section. Examples of such product are ''Mechanically Separated Chicken'' and ''Mechanically Separated Turkey.''

(b) ''Mechanically Separated (Kind of Poultry)'' shall not have a bone solids content of more than 1 percent. At least 98 percent of the bone particles present in ''Mechanically Separated (Kind of Poultry) '' shall have a maximum size no greater than 1.5 mm (millimeter) in their greatest dimension and there shall be no bone particles larger than 2.0 mm in their greatest dimension.

(c) ''Mechanically Separated (Kind of Poultry)'' shall not have a calcium content exceeding 0.235 percent when made from mature chickens or from turkeys as defined in § 381.170(a)(l)(vi) and (vii) and (a)(2), respectively, or 0.175 percent when made from other poultry, based on the weight of product that has not been heat treated, as a measure of a bone solids content of not more than 1 percent.

(d) ''Mechanically Separated (Kind of Poultry)'' may be used in the formulation of poultry products in accordance with § 381.174 and meat food products in accordance with subchapter A of this chapter.

(e) Product resulting from the mechanical separation process that fails to meet the bone particle size or calcium content requirements for ''Mechanically Separated (Kind of Poultry)'' shall be used only in producing poultry extractives, including fats, stocks, and broths and labeled as ''Mechanically Separated (Kind of Poultry) for Further Processing.''

[60 FR 55983, Nov. 3, 1995]

§ 381.174 Limitations with respect to use of Mechanically Separated (Kind of Poultry).

(a) A poultry product required to be prepared from a particular kind of poultry (e.g., chicken) shall not contain ''Mechanically Separated (Kind of Poultry)'' described in § 381.173, that is made from any other kind of poultry (e.g., Mechanically Separated Turkey).

(b) ''Mechanically Separated (Kind of Poultry)'' described in § 381.173 may be used in the formulation of any poultry or meat food product, provided such use conforms with any applicable requirements of the definitions and standards of identity or composition in this subchapter or part 319 of this chapter, and provided that it is identified as ''Mechanically Separated (Kind of Poultry).''

[60 FR 55983, Nov. 3, 1995]

Subpart Q—Records, Registration, and Reports

§ 381.175 Records required to be kept.

(a) Every person within any of the classes specified in paragraph (a) (1), (2), or (3) of this section is required by the Act to keep such records as are properly necessary for the effective enforcement of the Act:

(1) Any person that engages in the business of slaughtering any poultry or processing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as a poultry products broker, wholesaler, or otherwise) or transporting, in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any poultry;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.

(b) The required records are:

(1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any poultry or poultry carcass, or part or product of a poultry carcass, is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act.

(i) The name or description of the poultry or other articles;

(ii) The net weight of the poultry or other articles;

(iii) The number of outside containers;

(iv) The name and address of the buyer of the poultry or other articles sold by such person, and the name and address of the seller of the poultry or other articles purchased by such person;

(v) The name and address of the consignee or receiver (if other than the buyer);

(vi) The method of shipment;

(vii) The date of shipment; and

(viii) The name and address of the carrier.

(2) Guaranties provided by suppliers of packaging materials under § 381.144.

(3) Records of canning as required by part 431 of this chapter.

(4) Records of irradiation as required by sections 381.149 of this part.

(5) Records of nutrition labeling as required by subpart Y of this part.

(6) Records of all labeling, along with the product formula, processing procedures, and any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations and policies on labeling, as prescribed in § 412.1 of this chapter.

(Approved by the Office of Management and Budget under control number 0583–0015)

[37 FR 9706, May 16, 1972, as amended at 47 FR 746, Jan. 7, 1982; 49 FR 2236, Jan. 19, 1984; 51 FR 45633, Dec. 19, 1986; 57 FR 43600, Sept. 21, 1992; 58 FR 675, Jan. 6, 1993; 60 FR 67458, Dec. 29, 1995; 78 FR 66838, Nov. 7, 2013; 83 FR 25308, May 31, 2018]

§ 381.176 Place of maintenance of records.

Every person engaged in any business described in § 381.175(a) shall maintain the records required by § 381.175 at the place of business where such business is conducted, except that, if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§ 381.177 Record retention period.

(a) Every record required to be maintained under this subpart shall be retained for a period not to exceed 2 years after December 31 of the year in which the transaction to which the record relates has occurred, and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such record under this subpart.

(b) Records of canning as required by subpart X of this part 381, subchapter

C, 9 CFR chapter III, shall be retained as required in §381.307; except that records required by §381.302 (b) and (c) shall be retained as required by those sections.

[37 FR 9706, May 16, 1972, as amended at 51 FR 45633, Dec. 19, 1986]

§381.178 Access to and inspection of records, facilities and inventory; copying and sampling.

Representatives of the Secretary afforded access to a business specified in §381.175 of this part (see §300.6(b)(2) of this chapter) also must be afforded any necessary facilities (other than reproduction equipment) for the examination and copying of records and the examination and sampling of inventory.

[69 FR 255, Jan. 5, 2004]

§381.179 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer, or engages in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any poultry, whether intended for human food or other purposes, or engages in the business as a public warehouseman storing any such articles in or for commerce, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, shall register with the Administrator, giving such information as is required, including his name, and the address of each place of business at which, and all trade names under which he conducts such business. Such persons shall register under this section by filing with the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, a form containing such information, within 90 days after the effective date hereof or after such later date as he begins to engage in such business if not engaged therein upon said effective date. All information submitted shall be current and correct. The registration form shall be obtained from District Enforcement Operations, Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 or by calling the District Office.

(b) Whenever any change is made in the name of, or address of any place of business at which, or any trade name under which a registrant conducts his business, he shall report such change in writing to the Administrator within 15 days after making the change.

(c) The registration requirements prescribed in this section shall not apply to persons conducting any of the businesses specified in this section only at an official establishment.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 57 FR 53982, Nov. 16, 1992; 69 FR 255, Jan. 5, 2004]

§381.180 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection thereat, as may be required by the Administrator in special cases.

(b) The operator of each official establishment shall also make such other reports as the Administrator may from time to time require under the Act.

[37 FR 9706, May 16, 1972, as amended at 61 FR 38868, July 25, 1996]

§381.181 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Whenever the consignee of any poultry product which bears an official inspection legend refuses to accept delivery of such product on the grounds that it is adulterated or misbranded, the consignee shall notify the appropriate program supervisor, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, of the kind, quantity,

source and present location of the product and the respects in which it is alleged to be adulterated or misbranded, and it will be a violation of the Act for any person to sell or transport, or offer for sale or transportation or receive for transportation, in commerce, any such product which is capable of use as human food and is in fact adulterated or misbranded at the time of such sale, transportation, offer, or receipt: *Provided,* That any such allegedly adulterated or misbranded product may be transported to any official establishment for reinspection.

§ 381.182 Reports of inspection work.

Reports of the inspection work carried on within official establishments shall be forwarded to the Administrator by the inspector in charge in such a manner as may be specified by the Administrator.

Subpart R—Cooperation With States and Territories; Certification of State and Territorial Programs as at Least Equal to Federal Program

§ 381.185 Assistance to State and Territorial programs.

(a) The Administrator is authorized, under paragraph (a) of section 5 of the Act, when he determines it would effectuate the purposes of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering the poultry product inspection program of such jurisdiction, with a view to assuring that it imposes and enforces requirements at least equal to those under sections 2 through 4, 6 through 10, and 12 through 22 of the Act, with respect to establishments at which poultry are slaughtered or poultry products are processed for use as human food, solely for distribution within such jurisdiction, and with respect to the poultry products of such establishments. Such cooperation is authorized if the jurisdiction has enacted a mandatory law imposing ante mortem and post mortem inspection, reinspection, and sanitation requirements (at least equal to those under the Federal Act), with respect to all or certain classes of persons engaged in slaughtering poultry or otherwise processing poultry products for use as human food solely for distribution within such jurisdiction.

(b) The Administrator is also authorized under paragraph (a) of section 5 of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering programs under the laws of such jurisdiction containing authorities at least equal to those provided in section 11 of the Act (relating to records; registration of specified classes of operators; dead, dying, disabled, or diseased poultry; and products not intended for human food) when he determines that such cooperation would effectuate the purposes of the Act.

(c) Such cooperation may include advisory assistance, technical and laboratory assistance and training, and financial aid. The Federal contribution to any State (or territory) for any year shall not exceed 50 percent of the estimated total cost of the cooperative State (or territorial) program. A cooperative program under this section is called a State-Federal program.

§ 381.186 Cooperation of States and other jurisdictions in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized under stated conditions to utilize employees and facilities of any State in carrying out Federal functions under the Poultry Products Inspection Act. A cooperative program for this purpose is called a Federal-State program. Under paragraph (a) of section 5 of the Poultry Products Inspection Act, the Administrator is also authorized to conduct examinations, investigations, and inspections under the Act through any officer or employee of any State or territory or the District of Columbia commissioned by him for such purpose.

§ 381.187 Cooperation of States for the interstate shipment of poultry products.

(a) The Administrator is authorized under 21 U.S.C. 472(b) to coordinate with States that have poultry products inspection programs as provided in

§ 381.185 of this subpart to select certain establishments operating under these programs to participate in a cooperative program to ship poultry products in interstate commerce. A cooperative program for this purpose is called a ''cooperative interstate shipment program.''

(b) Establishments selected to participate in a cooperative interstate shipment program described in this section must receive inspection services from designated State personnel that have been trained in the enforcement of the Act. If the designated personnel determine that the poultry products prepared in establishments selected to participate in the cooperative interstate shipment program comply with all requirements under the Act, these items will bear an official Federal mark of inspection and may be shipped in interstate commerce. The Administrator will assign an FSIS ''selected establishment coordinator,'' who will be an FSIS employee, to each State that participates in a cooperative interstate shipment program to provide Federal oversight of the program and enforcement of the program's requirements. The Federal contribution for inspection services provided by States that enter into a cooperative interstate shipment program under this section will be at least 60 percent of eligible State costs. Eligible State costs are those costs that a State has justified and FSIS has approved as necessary for the State to provide inspection services to selected establishments in the State.

(c) Subpart Z, of this part 381 prescribes conditions under which States and establishments may participate in the cooperative interstate shipment program.

(d) The Administrator will terminate a cooperative interstate shipment agreement with a State if the Administrator determines that the State is not conducting inspection at selected establishments in a manner that complies with the Act and the implementing regulations in this chapter.

[76 FR 24756, May 2, 2011]

Subpart S—Transportation; Exportation; or Sale of Poultry or Poultry Products

§ 381.189 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this subpart do not apply:

(a) To dead, dying, disabled or diseased poultry and specimens of undenatured, uninspected or adulterated carcasses, parts, or products of poultry sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To dead, dying, disabled or diseased poultry and specimens of undenatured, uninspected or adulterated carcasses, parts, or products of poultry thereof for educational, research, or other nonfood purposes shipped under permit issued by the inspector in charge upon his determination that collection and movement thereof will not interfere with inspection or sanitary conditions at the establishment, and the specimens are for nonfood purposes. The person desiring such specimens shall make a written application to the inspector in charge for such permit on Form MP–112 and shall obtain permission from the operator of the official establishment to obtain the specimens. Permits shall be issued for a period not longer than one year. The permit may be revoked by the inspector in charge if he determines after notice and opportunity to present views is afforded to the permittee that any such specimens were not used as stated in the application, or if the collection or handling of the specimens interferes with inspection or the maintenance of sanitary conditions in the establishment. The specimens referred to in this paragraph shall be collected and handled only at such time and place and in such manner as not to interfere with the inspection or to cause any objectionable condition and shall be identified as inedible when they leave the establishment.

(c) To parts of poultry carcasses that are naturally inedible by humans, such

as entrails and feathers in their natural state.

[40 FR 55310, Nov. 28, 1975]

§ 381.190 Transactions in slaughtered poultry and other poultry products restricted; vehicle sanitation requirements.

(a) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce or from any official establishment, any slaughtered poultry from which the blood, feathers, feet, head, or viscera have not been removed in accordance with the regulations.

(b)(1) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any slaughtered poultry or other poultry product which is capable of use as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except as otherwise provided in this paragraph (b) and subpart C or T.

(2)(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment directly for export as human food, if they have been examined and found to be suitable for such purpose, by an inspector and are labeled as prescribed in this paragraph.

(ii) The containers of all such products shall bear a label showing: (A) The name of the products; (B) the name and address of the packer or distributor, and, when the name of the distributor is shown, it shall be qualified by such terms as ''packed for,'' ''distributed by,'' or ''distributors''; and (C) the official establishment number of the establishment where packed.

(iii) Such products shall not bear the official inspection legend.

(3)(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment and in commerce directly to another official establishment for processing before export, provided the receiving establishment maintains records that:

(A) Identify the source of the incoming undenatured poultry product;

(B) Identify the location of the product at all times during processing and preparation for export; and

(C) Contain a written certification from an official of the receiving establishment that the undenatured poultry product intended for export has not been, and will not be, commingled with any product intended for consumption in the United States.

(ii) The receiving establishment may only ship the undenatured poultry product intended for export in accordance with the inspection and labeling requirements of paragraph (b)(2) of this section.

(c) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, poultry products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under § 381.221, any poultry product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated. Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment. The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Inspection Service's discretion and shall be adequate to determine if poultry product in such conveyance is, or when moved could become, adulterated.

Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that poultry product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected. Poultry product placed in any means of conveyance that is found by the inspector to be in such condition that the poultry product may have become adulterated shall be removed from the means of conveyance and handled in accordance with § 381.145(b).

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 41 FR 23700, June 11, 1976; 60 FR 43358, Aug. 21, 1995]

§ 381.191 Distribution of inspected products to small lot buyers.

For the purpose of facilitating the distribution in commerce of inspected poultry products to small lot buyers (such as small restaurants), distributors or jobbers may remove inspected and passed non-consumer-packaged poultry carcasses or consumer-packaged poultry products from shipping containers or immediate containers, other than consumer packages, and place them into other containers which do not bear an official inspection mark: *Provided,* That the individual non-consumer-packaged carcasses bear the official inspection legend and the official establishment number of the establishment that processed the articles; and the consumer-packaged articles are fully labeled in accordance with subpart N: *And provided further,* That the other container is marked with the name and address of the distributor or jobber and bears the statement ''The poultry product contained herein was inspected by the U.S.D.A.'' in the case of poultry products processed in the United States, or the statement ''The poultry products contained herein have been approved for importation under P.P.I.A.'' in the case of imported poultry products.

§ 381.192 Penalties inapplicable to carriers.

No carrier shall be subject to the penalties of the Act, other than the penalties for violation of section 11, by reason of his receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of poultry or poultry products, owned by another person, unless the carrier has knowledge, or is in possession of facts which would cause a reasonable person to believe that such poultry or poultry products were not inspected or marked in accordance with the provisions of the Act or where otherwise not eligible for transportation under the Act, or unless the carrier refuses to furnish on request of a representative of the Secretary, the name and address of the person from whom he received such poultry or poultry products, and copies of all documents, if any there be, pertaining to the delivery of the poultry or poultry products to such carrier.

§ 381.193 Poultry carcasses, etc., not intended for human food.

(a) Except as provided in paragraph (b) of this section, poultry carcasses, and parts and products thereof, that are not intended for use as human food may, after they have been denatured as prescribed in § 381.95, be bought, sold, transported, offered for sale or transportation, or received for transportation, in commerce, or imported, even though they do not comply with all the provisions of the regulations, provided they are marked ''Not fit for human food.'' These requirements do not apply to parts of poultry carcasses that are naturally inedible by humans, such as entrails.

(b)(1) Except as provided in paragraphs (b) (2), (3), and (4) of this section, no animal food processed, in whole or in part, from materials derived from the carcasses of poultry in an official establishment or elsewhere, shall be bought, sold, transported, offered for sale or transportation, or received for transportation in commerce, or imported, unless:

(i) It is properly identified as animal food;

(ii) It is not represented as being a human food; and

(iii) It has been denatured as prescribed in § 381.95 so as to be readily distinguishable from an article of human food.

(2) Notwithstanding the provisions of paragraph (b)(1) of this section, an animal food that consists of less than 5 percent of parts or products of the carcasses of poultry and that is not represented by labeling or appearance or otherwise as being a human food or as a product of the poultry industry need not be denatured in accordance with § 381.95.

(3) Notwithstanding the provisions of paragraph (b)(1) of this section, animal food packed in hermetically sealed, retort processed, conventional retail-size containers, and retail-size packages of semi-moist animal food need not be denatured in accordance with § 381.95 if the name of the article clearly conveys the article's intended use for animal food and appears on the label in a conspicuous manner.

(i) Except as provided in paragraph (ii) of paragraph (b)(3) of this section, the name of the article must be stated on the label as ''Animal Food,'' ''Pet Food,'' or ''(name of species) Food'' (e.g., ''Dog Food'' or ''Cat Food''). To be considered conspicuous, the name of the article, wherever it appears on the label, must be stated in letters at least twice as high, wide, and thick as the letters indicating the presence in the article of any ingredients derived from carcasses of poultry.

(ii) Notwithstanding the provisions of paragraph (i) of paragraph (b)(3) of this section, the article's name may be stated on the label to show that it is or contains poultry carcass-source material and that the article is for animals; e.g., ''Chicken for Pets'' or ''Turkey Dinner for Cats'': *Provided,* That the entire name of the article is stated, wherever it appears on the label, as an individual, contiguous unit, whether stated on a single line or more than one line, and the letters denoting the article's intended use for animal food are at least as high, wide, and thick as the letters indicating the presence of material derived from any poultry carcass. However, when the label bears on its principal display panel a vignette which pictures, in clearly recognizable form and size, one or more animals of the species for which the article's name indicates the article is intended, the letters used to state the article's intended use shall be at least one-half as high, wide, and thick as the letters used in the article's name or other letters indicating the presence of material derived from any poultry carcass, but shall not be less than ⅛ inch high. The letters used to state the article's intended use may be separated from the article's name by the vignette.

(iii) Letters used to denote the intended use of the article must contrast as markedly with their background as the letters indicating the presence in the article of poultry carcass-source material contrast with their background.

(4) The requirements of this part do not apply to livestock or poultry feed manufactured from processed poultry byproducts (such as poultry byproduct meal, hydrolyzed poultry feathers, and hydrolyzed poultry byproducts aggregate), or to processed dry animal food.

[49 FR 47479, Dec. 5, 1984]

§ 381.194 Transportation and other transactions concerning dead, dying, disabled, or diseased poultry, and parts of carcasses of poultry that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation or receive for transportation, in commerce, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, unless such poultry and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required

by § 381.179, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by the Secretary as one that imposes requirements at least equal to the Federal requirements for purposes of section 5(c) of the Act.

(b) Buy in commerce or import any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by § 381.179, or is the operator of an establishment inspected as required by paragraph (a) of this section and such poultry or parts of carcasses are to be delivered to establishments eligible to receive them under paragraph (a) of this section.

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided,* That any such dead, dying, disabled, or diseased poultry, or parts of carcasses may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier shall immediately report the facts by telegraph or telephone to the Director, Compliance Staff, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[40 FR 55310, Nov. 28, 1975]

Subpart T—Imported Poultry Products

§ 381.195 Definitions; requirements for importation into the United States.

(a) When used in this part, the following terms are defined to mean:

(1) *Import (imported).* To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer(ed) for entry.* The point at which the importer presents the imported product for reinspection.

(3) *Entry (entered).* The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection, as required by § 381.204.

(b) No slaughtered poultry, or parts or products thereof, shall be imported into the United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, adulterated, or unfit for human food and they also comply with the regulations prescribed in this subpart to assure that they comply with the standards provided for in the Act: *Provided,* That the provisions of this subpart apply to such articles only if they are capable of use as human food.

(c) Except as provided in § 381.207, slaughtered poultry and other poultry products may be imported only if they were processed solely in countries listed in § 381.196(b). Slaughtered poultry may be imported only if it qualifies as ready-to-cook poultry.

[37 FR 9706, May 16, 1972, as amended at 40 FR 42338, Sept. 12, 1975; 54 FR 41049, Oct. 5, 1989; 79 FR 56233, Sept. 19, 2014]

§ 381.196 Eligibility of foreign countries for importation of poultry products into the United States.

(a)(1) Whenever it shall be determined by the Administrator that the system of poultry inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their poultry products, with requirements equivalent to all the provisions of the Act and the regulations in this part which are applied to official establishments in the United States, and their poultry products, and that reliance can be placed upon certificates required under this subpart from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, poultry products processed in such establishments which

are certified and approved in accordance with paragraph (a)(3) of this section shall be eligible, so far as the regulations in this part are concerned, for importation into the United States from such foreign country after applicable requirements of this part have been met.

(2) The determination of acceptability of a foreign poultry inspection system for purposes of this section shall be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system shall have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of poultry inspection in the United States with respect to:

(A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which poultry products are processed for export to the United States;

(B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system;

(C) The assignment of competent, qualified inspectors;

(D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing poultry inspection and to certify or refuse to certify poultry products intended for export;

(E) Adequate administrative and technical support;

(F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States.

(G) Other requirements of adequate inspection service as required by the regulations.

(ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of poultry inspection organized and maintained in the United States with respect to:

(A) Ante mortem inspection of poultry for slaughter, which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of veterinarians;

(B) Post mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians;

(C) Official controls by the national government over establishment construction, facilities, and equipment;

(D) Direct and continuous official supervision of slaughtering of poultry and processing of poultry products, by the assignment of inspectors to establishments certified under paragraph (a)(3) of this section to assure that adulterated or misbranded poultry products are not processed for export to the United States;

(E) Complete separation of establishments certified under subparagraph (3) of this paragraph from establishments not certified, and the maintenance of a single standard of inspection and sanitation throughout all certified establishments;

(F) Requirements for sanitation at certified establishments and for sanitary handling of poultry products;

(G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment;

(H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.

(I) Other matters for which requirements are contained in the Act or the regulations in this part.

(iii) Countries desiring to establish eligibility for importation of poultry products into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign poultry inspection system is based and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a)(2) (i) and (ii). Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in

paragraphs (a)(2) (i) and (ii) of this section. Maintenance of eligibility of a country for importation of poultry products into the United States depends on the results of periodic reviews of the foreign poultry inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system as the Administrator may find pertinent to and necessary for the determinations required by this section.

(iv) The foreign inspection system must maintain a program to assure that the requirements referred to in this section, equivalent to those applicable to the Federal system in the United States, are being met. The program as implemented must provide for the following:

(A) Periodic supervisory visits by a representative of the foreign inspection system to each establishment certified in accordance with paragraph (a)(3) of this section to ensure that requirements referred to in paragraphs (a)(2)(ii)(A) through (H) of this section are being met: Provided, That such visits are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States;

(B) Written reports prepared by the representative of the foreign inspection system who has conducted a supervisory visit, documenting his or her findings with respect to the requirements referred to in paragraphs (a)(2)(ii)(A) through (a)(2)(ii)(H) of this section, copies of which shall be made available to the representative of the Department at the time of the representative's review upon request by that representative to a responsible foreign inspection official: *Provided*, that such reports are not required during a period when the establishment is not operating or not engaged in producing products for exportation to the United States.

(C) Random sampling and testing at the point of slaughter of carcasses, including internal organs and fat, for residues identified by the exporting country's inspection authorities or by this Agency as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator: *Provided*, that such testing is required only on samples taken of carcasses from which poultry or poultry products intended for importation into the United States are produced.

(3) Only those establishments that are determined and certified to the Agency by a responsible official of the foreign meat inspection system as fully meeting the requirements of paragraphs (a)(2)(i) and (ii) of this section are eligible to have their products imported into the United States. Establishment eligibility is subject to review by the Agency (including observations of the establishments by Program representatives at times prearranged with the foreign meat inspection system officials). Foreign establishment certifications must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may terminate the eligibility of any foreign establishment for the importation of its products into the United States if it does not comply with the requirements listed in paragraphs (a)(2)(i) and (ii) of this section, or if current establishment information cannot be obtained. The Administrator will provide reasonable notice to the foreign government of the proposed termination of any foreign establishment, unless a delay in terminating its eligibility could result in the importation of adulterated or misbranded product.

(i) For a new establishment or any establishment for which information from last year's electronic certification or paper certificate has changed, the certification or certificate must contain: The date; the foreign country; the foreign establishment's name, address, and foreign establishment number; the foreign official's title; the foreign official's signature (for paper certificates only); the type of operation(s) conducted at the establishment (e.g., slaughter, processing, storage, exporting warehouse); and the establishment's eligibility status (e.g., new or relisted (if previously delisted)). Slaughter and processing establishment certifications must address the species and type of products produced at the establishment (e.g., the process category).

(ii) If the establishment information provided on the preceding year's electronic foreign establishment certification or paper certificate, as required in paragraph (a)(3)(i) of this section, has not changed, the certification or certificate must contain: The date, the foreign country, the foreign establishment's name, the foreign official's title and signature (for paper certificates only).

(4) Poultry products from foreign countries not listed in paragraph (b) of this section are not eligible for importation into the United States, except as provided by §§ 381.207 and 381.209. The listing of any foreign country under this section may be withdrawn whenever it shall be determined by the Administrator that the system of poultry inspection maintained by such foreign country does not assure compliance with requirements equivalent to all the requirements of the Act and the regulations as applied to official establishments in the United States; or that reliance cannot be placed upon certificates required under this subpart from authorities of such foreign country; or that, for lack of current information concerning the system of poultry inspection being maintained by such foreign country, such foreign country should be required to reestablish its eligibility for listing.

(b) It has been determined that poultry products from the following countries, covered by foreign poultry inspection certificates of the country of origin as required by § 381.197, are eligible under the regulations in this subpart for entry into the United States, after inspection and marking as required by the applicable provisions of this subpart: [1]

Australia (ratites only).
Canada.
Chile.
France.
Great Britain.
Hong Kong.
Israel.
Mexico. [2]
New Zealand (ratites only).
People's Republic of China. [2]
Republic of Korea

[37 FR 9706, May 16, 1972, as amended at 43 FR 8117, Feb. 28, 1978; 52 FR 23021, June 17, 1987; 54 FR 41049, Oct. 5, 1989; 54 FR 43951, Oct. 30, 1989; 60 FR 38668, July 28, 1995; 61 FR 38868, July 25, 1996; 64 FR 49645, Sept. 14, 1999; 68 FR 37071, June 23, 2003; 71 FR 20871, Apr. 24, 2006; 71 FR 43961, Aug. 3, 2006; 72 FR 61796, Nov. 1, 2007; 79 FR 16661, Mar. 26, 2014; 79 FR 56234, Sept. 19, 2014]

§ 381.197 Foreign inspection certificate requirements.

(a) Except as provided in §§ 381.207 and 381.209, each consignment imported into the United States must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product.

(b) An official of the foreign government must certify that any product described on any official certificate was produced in accordance with the regulatory requirements in § 381.196.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; and bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date;

(2) The foreign country of export and the producing foreign establishment number;

[1] Listing of any country in this section does not relieve the poultry products of such country from applicable requirements under other Federal laws.

[2] May export to the United States only processed poultry products slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry products to the United States.

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification mark on the units;

(8) The net weight of each lot; and

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

[79 FR 56234, Sept. 19, 2014]

§ 381.198 Import inspection application.

(a) Applicants must submit an import inspection application to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted (electronically or on paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 381.207 and 381.209.

[79 FR 56234, Sept. 19, 2014]

§ 381.199 Inspection of poultry products offered for entry.

(a)(1) Except as provided in § 381.209 and paragraph (c) of this section, all slaughtered poultry and poultry products offered for entry from any foreign country shall be reinspected by a Program import inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection for appearance and condition, and checked for certification and label compliance.

(3) The electronic inspection system shall be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic inspection system.

(b) Inspectors may take, without cost to the United States, from each consignment of poultry products offered for entry, such samples of the products as are deemed necessary to determine the eligibility of the products for entry into the commerce of the United States.

(c) Poultry products imported under § 381.207 shall not be sampled and inspected under this section unless there is reason for suspecting the presence therein of a substance in violation of that section, and in such case they shall be sampled and inspected in accordance with paragraph (a) of this section.

(d) In addition to the provisions specified in paragraphs (a), (b), and (c) of this section, the following requirements apply to imported canned product.

(1) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(i) If the defective containers are not indicative of an unsafe or unstable product as determined by the Administrator;

(ii) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(iii) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(2) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under the supervision of such inspectors in accordance with §381.309 (d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(*c*), (d)(1)(v), (d)(1)(vii), and (d)(1)(viii) of this subchapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with §381.309(d)(1)(i) of this subchapter.

(3) Sampling plans and acceptance levels as prescribed in paragraphs (d)(1) and (d)(2) of this section may be obtained, upon request, from International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(e) All products, required by this part to be inspected, shall be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section. Such approved official import inspection establishments will be listed in the Meat, Poultry and Egg Product Inspection Directory, published by the Food Safety and Inspection Service. The listing will categorize the kind or kinds of product which may be inspected at each official import inspection establishment, based on the adequacy of the facilities for making such inspections and handling such products in a sanitary manner.

(f) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application shall be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, and shall include all information called for by that form.

(g) Approval for Federal import inspection shall be in accordance with subpart D of this part.

(h) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§381.21 and 381.36, and part 416 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(i) The Administrator is authorized to approve any establishment as an official import inspection establishment provided that an application has been filed and drawings have been submitted in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(j) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may also be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(k) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

[37 FR 9706, May 16, 1972, as amended at 49 FR 36819, Sept. 20, 1984; 51 FR 45633, Dec. 19, 1986; 54 FR 275, Jan. 5, 1989; 54 FR 41050, Oct. 5, 1989; 79 FR 56234, Sept. 19, 2014]

§ 381.200 Poultry products offered for entry, retention in customs custody; delivery under bond; movement prior to inspection; handling; facilities and assistance.

(a) No slaughtered poultry or other poultry product required by this subpart to be inspected shall be released from customs custody prior to inspection, but such product may be delivered to the consignee, or his agent, prior to inspection, if the consignee shall furnish a bond, in form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through the customs.

(b) Except as provided in paragraph (a) of this section, no product required by this subpart to be inspected shall be moved, prior to inspection, from the port of arrival where first unloaded, and if arriving by water, from the wharf where first unloaded at such port, to any place other than the place designated in accordance with this subpart as the place where the same shall be inspected; and no product shall be conveyed in any manner other than in compliance with this subpart.

(c) The consignee, or his agent, shall furnish such facilities and shall provide such assistance for handling and marking poultry products offered for entry as the inspector may require.

[37 FR 9706, May 16, 1972, as amended at 51 FR 37710, Oct. 24, 1986; 54 FR 41050, Oct. 5, 1989; 56 FR 65180, Dec. 16, 1991]

§ 381.201 Means of conveyance and equipment used in handling poultry products offered for entry to be maintained in sanitary condition.

Compartments of steamships, railroad cars, and other means of conveyance transporting any poultry product to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any poultry product offered for entry into the United States, shall be maintained in a sanitary condition.

§ 381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

(a)(1) Program inspectors shall report their findings as to any product which has been inspected in accordance with this part, to the Director of Customs at the original port of entry.

(2) When product has been identified as ''U.S. refused entry,'' the inspector shall request the Director of Customs to refuse admission to such product and to direct that it be exported by the owner or consignee within the time specified in this section, unless the owner or consignee, within the specified time, causes it to be destroyed by disposing of it under the supervision of a Program employee so that the product can no longer be used as human food, or by converting it to animal food uses, if permitted by the Food and Drug Administration. The owner or consignee of the refused entry product shall not transfer legal title to such product, except to a foreign consignee for direct and immediate exportation, or an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food purposes. ''Refused entry'' product must be delivered to and used by the manufacturer or renderer within the 45-day time limit. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed as specified in the notice under paragraph (a)(4) of this section.

(3) No lot of product which has been refused entry may be subdivided during disposition pursuant to paragraph (a)(2) of this section, except that removal and destruction of any damaged or otherwise unsound product from a lot destined for reexportation is permitted under supervision of USDA prior to exportation. Additionally, such refused entry lot may not be shipped for export from any port other than that through which the product came into the United States without the expressed consent of the Administrator, based on full information concerning the product's disposition, including the name of the vessel and the date of export. For the purposes of this

paragraph, the term ''lot'' shall refer to that product identified on MP Form 410 in the original request for inspection for importation pursuant to § 381.198.

(4) The owner or consignee shall have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in paragraph (a)(2) of this section for ''refused entry'' product. Extension beyond the 45-day period may be granted by the Administrator when extreme circumstances warrant it; e.g., a dock workers' strike or an unforeseeable vessel delay.

(5) If the owner or consignee fails to take the required action within the time specified under paragraph (a)(4) of this section, the Department will take such actions as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expenses in the appropriate forum.

(6) No product which has been refused entry and exported to another country pursuant to paragraph (a)(2) of this section may be returned to the United States under any circumstance. Any such product so returned to the United States shall be subject to administrative detention in accordance with section 19 of the Act, and seizure and condemnation in accordance with section 20 of the Act.

(b) Upon the request of the Director of Customs at the port where a product is offered for clearance through the customs, the consignee of the product shall, at the consignee's own expense, immediately return to the Director any product which has been delivered to consignee under this subpart and subsequently designated ''U.S. Refused Entry'' or found in any request not to comply with the requirements in this subpart.

(c) Except as provided in § 381.200(a) or (b), no person shall remove or cause to be removed from any place designated as the place of inspection, any poultry product which the regulations in this subpart require to be marked in any way, unless the same has been clearly and legibly marked in compliance with this subpart.

(d) Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided,* That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, and such supervisor shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate supervisor of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

(e) All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues, shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishments.)

(1) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. (Tanks and equipment used for this purpose or for rendering or preparing inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection by means of pipes, or otherwise, between tanks containing inedible products and those containing edible products.)

(2) Incineration or complete destruction by burning.

(3) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(i) Crude carbolic acid,

(ii) Kerosene, fuel oil, or used crankcase oil, or

(iii) Any phenolic disinfectant conforming to commercial standards CS 70–41 or CS 71–41 which shall be used in at least 2 percent emulsion or solution.

(4) Any other substances or method that the Administrator approves in specific cases, which will denature the poultry product to the extent necessary to accomplish the purposes of this section.

(5) Carcasses and parts of carcasses condemned for biological residue shall be disposed of in accordance with paragraph (e)(2) of this section or by burying under the supervision of an inspector.

[37 FR 9706, May 16, 1972, as amended at 48 FR 15890, Apr. 13, 1983; 50 FR 19908, May 13, 1985; 51 FR 37709, Oct. 24, 1986; 53 FR 17015, May 13, 1988; 54 FR 50735, Dec. 11, 1989; 60 FR 67458, Dec. 29, 1995]

§ 381.203 Products offered for entry; charges for storage, cartage, and labor with respect to products which are refused entry.

All charges for storage, cartage, and labor with respect to any product offered for entry which is refused entry pursuant to the regulations shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any other products offered for entry thereafter by or for such owner or consignee.

[54 FR 41050, Oct. 5, 1989]

§ 381.204 Marking of poultry products offered for entry; official import inspection marks and devices.

(a) Except for products offered for entry from Canada, poultry products which upon reinspection are found to be acceptable for entry into the United States shall be marked with the official inspection legend shown in paragraph (b) of this section. Such inspection legend shall be placed upon such products only after completion of official import inspection and product acceptance.

(b) The official mark for marking poultry products offered for entry as ''U.S. inspected and passed'' shall be in the following form, and any device approved by the Administrator for applying such mark shall be an official device.[2]

FIGURE 1

(c) When products are refused entry into the United States, the official mark to be applied to the products refused entry shall be in the following form:

UNITED STATES
REFUSED ENTRY

FIGURE 2

(d) The import warning notice prescribed in § 381.200(c) is an official mark.

(e) The ordering and manufacture of brands shall be in accordance with the provisions contained in § 317.3(c) of the Federal meat inspection regulations.

[2] The number ''I–42'' is given as an example only. The establishment number of the official establishment or official import inspection establishment where the product was inspected shall be shown on each stamp impression.

(f) The inspection legend may be placed on containers of product before completion of official import inspection if the containers are being inspected by an import inspector who reports to an Import Field Office Supervisor, the product is not required to be held at the establishment pending the receipt of laboratory test results; and a written procedure for controlled stamping, submitted by the import establishment and approved by the Director, Import Inspection Division, is on file at the import inspection facility where the inspection is to be performed.

(1) The written procedure for controlled pre-stamping should be in the form of a letter and shall include the following:

(i) That stamping under this subpart will be limited to those lots of product which can be inspected on the day that certificates for the product are examined;

(ii) That all products which have been pre-stamped will be stored in the facility where the import inspection will occur;

(iii) That inspection marks applied under this part will be removed from any lot of product subsequently refused entry on the day the product is rejected; and

(iv) That the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of origin, the foreign establishment number, the product name, the number of units, the shipping container marks, and the MP–410 number covering the product to be inspected. The daily stamping log must be retained by the establishment in accordance with the requirements of § 381.177.

(2) An establishment's controlled pre-stamping privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this subpart or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping privilege has been cancelled may appeal the decision to the Administrator, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the controlled pre-stamping was wrongfully cancelled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator. The cancellation of the controlled pre-stamping privilege will be in effect until there is a final determination in the proceeding.

(Approved by the Office of Management and Budget under control number 0583–0015)

[51 FR 37710, Oct. 24, 1986, as amended at 53 FR 17015, May 13, 1988; 54 FR 41050, Oct. 5, 1989]

§ 381.205 Labeling of immediate containers of poultry products offered for entry.

(a) Immediate containers of poultry products imported into the United States shall bear a label printed in English showing in accordance with subpart N of this part all information required by that section (except that the inspection mark and establishment number assigned by the foreign poultry inspection system and certified to the Inspection Service shall be shown instead of the official dressed poultry identification mark or other official inspection legend, and official establishment number); and in addition the label shall show the name of the country of origin preceded by the words ''Product of,'' which statement shall appear immediately under the name of the product.

(b) The labels shall not be false or misleading in any respect.

(c) All marks and other labeling for use on or with immediate containers must be approved for use by the Food Safety and Inspection Service in accordance with part 412 of this chapter before products bearing such marks

and other labeling will be permitted for entry into the United States.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 54 FR 41050, Oct. 5, 1989; 60 FR 67458, Dec. 29, 1995; 78 FR 66838, Nov. 7, 2013]

§ 381.206 Labeling of shipping containers of poultry products offered for entry.

Shipping containers of imported poultry products are required to bear in a prominent and legible manner the name of the product, the name of the country of origin, the foreign inspection system establishment number of the establishment in which the product was processed, and the inspection mark of the country of origin. Labeling on shipping containers shall be examined at the time of inspection in the United States and if found to be false or misleading, the product shall be refused entry. All labeling used with a shipping container of imported poultry products must be approved in accordance with subpart N of this part.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989; 60 FR 67458, Dec. 29, 1995]

§ 381.207 Small importations for consignee's personal use, display, or laboratory analysis.

Any poultry product (other than one which is forbidden entry by other Federal law or regulation) from any country in quantities of less than 50 pounds net weight, exclusively for the personal use of the consignee, or for display or laboratory analysis by the consignee, and not for sale or distribution; which is sound, healthful, wholesome, and fit for human food, and which is not adulterated and contains no substance not permitted by the Act or regulations, may be imported into the United States without a foreign inspection certificate, and such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part, except as provided in §381.199(c): *And provided,* That the Department may with respect to any specific importation, require that the consignee certify that such product is exclusively for the personal use of said consignee, or for display or laboratory analysis by said consignee, and not for sale or distribution.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989]

§ 381.208 Poultry products offered for entry and entered to be handled and transported as domestic; entry into official establishments; transportation.

(a) All poultry products, after entry into the United States in compliance with this subpart, shall be deemed and treated and, except as provided in §381.207, shall be handled and transported as domestic products, and shall be subject to the applicable provisions of this part and to the provisions of the Poultry Products Inspection Act and the Federal Food, Drug, and Cosmetic Act.

(b) Poultry products entered in accordance with this subpart may, subject to the provisions of the regulations, be taken into official establishments and be mixed with or added to poultry products that are inspected and passed or exempted from inspection in such establishments.

(c) Imported poultry products which have been inspected, passed, and marked under this subpart may be transported in commerce, only upon compliance with the applicable regulations.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989]

§ 381.209 Returned United States inspected and marked poultry products; exemption.

Poultry products which have been inspected and passed by the U.S. Department of Agriculture and are so marked, and are returned from foreign countries, may be imported if they are not adulterated or misbranded at the time of such return. Such products are exempted from further requirements under this part. Such returned shipments shall be reported to the Administrator by letter prior to arrival at the United States port of entry.

Subpart U—Detention; Seizure and Condemnation; Criminal Offenses

§ 381.210 Poultry and other articles subject to administrative detention.

Any poultry carcass, or part thereof; or any product made wholly or in part from any poultry carcass or part thereof; or any dead, dying, disabled, or diseased poultry is subject to detention for a period not to exceed 20 days when found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in commerce or otherwise subject to the Act, and there is reason to believe that any such poultry or other article is adulterated or misbranded and is capable of use as human food or has not been inspected, in violation of the provisions of the Act, any other Federal law, or the laws of any State or territory, or the District of Columbia; or that it has been or is intended to be distributed in violation of the provisions of the Act, any other Federal law, or the laws of any State or territory, or the District of Columbia.

§ 381.211 Method of detention; form of detention tag.

An authorized representative of the Secretary shall detain any poultry or other article to be detained under this subpart, by affixing an official ''U.S. Detained'' tag (FSIS Form 8400–2) to such article.

[55 FR 47843, Nov. 16, 1990]

§ 381.212 Notification of detention to the owner of the poultry or other article, or the owner's agent, and person having custody.

(a) When any poultry or other article is detained under this subpart, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the poultry or other article detained, and

(2) Promptly furnish a copy of a completed ''Notice of Detention'' (FSIS Form 8080–1) to the immediate custodian of the detained poultry or other article.

(b) If the owner of the detained poultry or other article, or the owner's agent, is not the immediate custodian at the time of detention and if the owner, or owner's agent, can be ascertained and notified, an authorized representative of the Secretary shall furnish a copy of the completed ''Notice of Detention'' to the owner, or the owner's agent. Such copy shall be served, as soon as possible, by delivering the notification to the owner, or the owner's agent, or by certifying and mailing the notification to the owner, or the owner's agent, at his or her last known residence or principal office or place of business.

[55 FR 47843, Nov. 16, 1990]

§ 381.213 Notification of governmental authorities having jurisdiction over article detained; form of written notification.

Within 48 hours after the detention of any poultry or other article pursuant to § 381.211, an authorized representative of the Secretary shall give oral or written notification of such detention to any Federal authorities not connected with the Inspection Service, and any State or other governmental authorities, having jurisdiction over such article. In the event notification is given orally, it shall be confirmed in writing, as promptly as circumstances permit.

§ 381.214 Movement of poultry or other article detained; removal of official marks.

(a) No poultry or other article detained in accordance with the provisions in this subpart shall be moved by any person from the place at which it is located when so detained, until released by an authorized representative of the Secretary: *Provided,* That any such article may be moved from the place at which it is located when so detained, for refrigeration or freezing, or storage purposes if such movement has been approved by an authorized representative of the Secretary and the article so moved will be further detained by an authorized representative of the Secretary after such movement.

(b) Upon terminating the detention of such article, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the released article, and

(2) Furnish copies of a completed ''Notice of Termination of Detention'' (FSIS Form 8400–1) to the persons notified when the article was detained. The notice shall be served by either delivering the notice to such persons or by certifying and mailing the notice to such persons at their last known residences or principal offices or places of business.

(c) All official marks may be required by such representative to be removed from such article before it is released unless it appears to the satisfaction of the representative that the article is eligible to retain such marks.

[37 FR 9706, May 16, 1972, as amended at 55 FR 47843, Nov. 16, 1990]

§ 381.215 Poultry or other articles subject to judicial seizure and condemnation.

Any poultry carcass, or part thereof, or any product made wholly or in part from any poultry carcass or part thereof; except those exempted from the definition of a poultry product in § 381.15, or any dead, dying, disabled, or diseased poultry, that is being transported in commerce or is otherwise subject to the Act, or is held for sale in the United States after such transportation, is subject to seizure and condemnation, in a judicial proceeding pursuant to section 20 of the Act if such poultry or other article:

(a) Is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of the Act; or

(b) Is capable of use as human food and is adulterated or misbranded; or

(c) In any other way is in violation of the Act.

§ 381.216 Procedure for judicial seizure, condemnation, and disposition.

Any poultry or other article subject to seizure and condemnation under this subpart is liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any U.S. district court, or other proper court specified in section 21 of the Act, within the jurisdiction of which the article is found.

§ 381.217 Authority for condemnation or seizure under other provisions of law.

The provisions of this subpart relating to detention, seizure, condemnation and disposition of poultry or other articles do not derogate from authority for retention, condemnation, or seizure conferred by other provisions of the Act, or other laws.

§ 381.218 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to forcible assaults on, or other interference with, any person while engaged in, or on account of the performance of, his official duties under the Act. Criminal provisions with respect to gifts or offers of bribes to such persons and related offenses are contained in the general criminal code (18 U.S.C. 201).

Subpart V—Special Provisions for Designated States and Territories; Criteria and Procedure for Designating Establishments With Operations Which Would Clearly Endanger the Public Health; Disposition of Poultry Products Therein

§ 381.220 Definition of "State".

For purposes of this subpart, the term ''State'' means any State (including the Commonwealth of Puerto Rico) or organized territory.

§ 381.221 Designation of States under paragraph 5(c) of the Act.

Each of the following States has been designated, under paragraph 5(c) of the Act, as a State in which the provisions of sections 1 through 4, 6 through 10, and 12 through 22 of the Act shall apply to operations and transactions wholly within the State. The Federal provisions apply, effective on the dates shown below:

States	Effective date of application of Federal provisions
Alaska	July 31, 1999.
Arkansas	Jan. 2, 1971.
California	Apr. 1, 1976.

States	Effective date of application of Federal provisions
Colorado	Jan. 2, 1971.
Connecticut	Oct. 1, 1975.
Florida	Dec. 2, 1997.
Georgia	Jan. 2, 1971.
Guam	Jan. 21, 1972.
Hawaii	Nov. 1, 1995.
Idaho	Jan. 2, 1971.
Kentucky	July 28, 1971.
Maryland	Mar. 31, 1991.
Massachusetts	Jan. 12, 1976.
Michigan	Jan. 2, 1971.
Nebraska	July 28, 1971.
Nevada	July 1, 1973.
New Hampshire	Aug. 6, 1978
New Jersey	Do.
New Mexico	Aug. 13, 2007.
New York	Apr. 10, 1977.
Northern Mariana Islands	Oct. 29, 1979.
Oregon	Jan. 2, 1971.
Pennsylvania	Oct. 31, 1971.
Puerto Rico	Jan. 17, 1972.
Rhode Island	Oct. 1, 1981.
South Dakota	Jan. 2, 1971.
Tennessee	Oct. 1, 1975.
Virgin Islands	Nov. 27, 1971.
Washington	June 1, 1973.

[42 FR 2949, Jan. 14, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 381.221, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 381.222 States designated under paragraph 5(c) of the Act; application of regulations.

The provisions of the regulations in this part apply to operations and transactions wholly within each State designated in § 381.221 under paragraph 5(c) of the Act, except as otherwise provided in this section. (The provisions of the regulations apply in all respects to operations and transactions in or for commerce.)

(a) Each establishment located in such a designated State, shall be granted inspection required under § 381.6(b) only if it is found, upon a combined evaluation of its premises, facilities, and operating procedures, to be capable of producing products that are not adulterated or misbranded.

(b) Section 381.26 will apply to establishments required to have inspection under § 381.6(b), except that existing interconnections between official and unofficial establishments or between official establishments will be permitted if it is determined in specific cases that the interconnections are such that transfer of inedible poultry product into the official establishment would be difficult or unusual, and any such transfers are strictly prohibited, except as permitted under other provisions of the regulations. It is essential that separation of facilities be maintained to the extent necessary to assure that inedible poultry product does not enter the official establishment contrary to the regulations.

(c) Sections 381.49 and 381.51 shall apply to such establishments, except that separate facilities for men and women workers will not be required when the majority of the workers in the establishment are related by blood or marriage, provided that this will not conflict with municipal or State requirements; and except that separation of toilet soil lines from house drainage lines to a point outside the buildings will not be required in existing construction when positive acting backflow devices are installed.

(d) Subpart N of this part shall apply to such establishments except as provided in this paragraph (d).

(1) The operator of each such establishment shall, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use (upon the date of inauguration of inspection) to the Front Line Supervisor in which the establishment is located. Temporary approval, pending formal approval under § 412.1 of this chapter, will be granted by the Front Line Supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by section 4(h) of the Act.

(2) The Front Line Supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the FSIS Labeling

and Program Delivery Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Front Line Supervisor (showing any modifications required by the Front Line Supervisor) to the FSIS Labeling and Program Delivery Staff at headquarters, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Front Line Supervisor must receive approval as required by §412.1 or their use must be discontinued.

(4) The Front Line Supervisor will also review all shipping containers to ensure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of pressure sensitive tape of a type that cannot be removed without visible evidence of such removal, or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of the regulations must be destroyed or removed from the official establishment.

(e) Sections 381.175 through 381.179 apply to operations and transactions not in or for commerce in a State designated under paragraph 5(c) only if the State is also designated under section 11 of the Act and if such provisions are applicable as shown in §381.224.

(f) Section 381.185(a) will not apply to States designated under paragraph 5(c) of the Act.

(g) Provisions of this part relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 62 FR 45027, Aug. 25, 1997; 78 FR 66838, Nov. 7, 2013]

§ 381.223 Control and disposition of nonfederally inspected poultry products in States designated under paragraph 5(c) of the Act.

Upon the effective date of designation of a State under paragraph 5(c) of the Act, no poultry products can be processed within the State unless they are prepared under inspection pursuant to the regulations or are exempted from the requirement of inspection under §381.10, and no unexempted poultry products which were processed without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, poultry products which were processed in any State listed in §381.187 and inspected and passed under the supervision of a responsible State or local inspection agency or exempted from State inspection can be distributed solely within the State, provided they are not adulterated or misbranded, except that the official inspection legend shall not be used. Such products may not enter official establishments. After said 90-day period, only federally inspected and passed products may be distributed within the designated State, except as provided in §381.10.

§ 381.224 Designation of States under section 11 of the Act; application of sections of the Act and the regulations.

Each of the following States has been designated, effective on the date shown below, under section 11 of the Act, as a State in which the provisions of the sections of the Act and regulations specified below shall apply to operators engaged, other than in or for commerce, in the kinds of business indicated below:

Paragraphs of act and regulations	Classes of operators	State	Effective date
Act, 11(b): §§ 381.175–381.178.	Persons engaged (not in or for commerce) in (1) the business of slaughtering any poultry or processing, freezing, packaging, or labeling any poultry carcasses, or parts or products thereof, for use as human food or animal food; (2) the business of buying or selling (as a poultry products broker, wholesaler, or otherwise), transporting or storing any poultry carcasses, or parts or products thereof; or (3) business as a renderer or in the business of buying, selling, or transporting any dead, dying, disabled, or diseased poultry or parts of carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Apr. 1, 1976.
		California	July 1, 1975.
		Colorado	Oct. 1, 1975.
		Connecticut	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Apr. 18, 1973.
		Kentucky	Nov. 12, 1976.
		Maryland	Jan. 12, 1976.
		Massachusetts	Nov. 12, 1976.
		Michigan	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Oct. 29, 1979.
		New Hampshire	July 1, 1975.
		New Jersey	July 16, 1975.
		New York	July 23, 1973.
		Northern Mariana Islands.	Oct. 29, 1979.
			Jan. 31, 1975.
		Oregon	
		Pennsylvania	May 2, 1974.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		South Dakota	Nov. 12, 1976.
		Tennessee	Oct. 1, 1975.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.
			Nov. 12, 1976.
Act, 11(c); § 381.179	Persons engaged (not in or for commerce) in business as a poultry products broker; renderer; animal food manufacturer; wholesaler or public warehouseman of poultry carcasses, or parts or products thereof; or buying, selling, or transporting dead, dying, disabled, or diseased poultry or parts of carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Apr. 1, 1976.
		California	July 1, 1975.
		Colorado	Oct. 1, 1975.
		Connecticut	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Apr. 18, 1973.
		Kentucky	Nov. 12, 1976.
		Maryland	Jan. 12, 1976.
		Massachusetts	Nov. 12, 1976.
		Michigan	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Oct. 29, 1979.
		New Hampshire	July 1, 1975.
		New Jersey	July 16, 1975.
		New York	July 23, 1973.
		Northern Mariana Islands.	Oct. 29, 1979.
			Jan. 31, 1975.
		Oregon	
		Pennsylvania	May 2, 1974.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		South Dakota	Nov. 12, 1976.
		Tennessee	Oct. 1, 1975.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.
			Nov. 12, 1976.

Paragraphs of act and regulations	Classes of operators	State	Effective date
Act, 11(d); 381.194	Persons engaged (not in or for commerce) in the business of buying, selling or transporting any dead, dying, disabled or diseased poultry, or parts or carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Nov. 12, 1976.
		Maryland	Nov. 12, 1976.
		Michigan	Oct. 29, 1979.
		New Hampshire ..	Oct. 29, 1979.
		Northern Mariana Islands.	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Nov. 19, 1976.
		Virgin Islands	Nov. 12, 1976.

[37 FR 9706, May 16, 1972; 65 FR 6888, Feb. 11, 2000]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §381.224, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 381.225 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of poultry products therein.

(a) An establishment in any State not listed in §381.221 that is preparing poultry products solely for distribution within such State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

(1) Any poultry product processed at the establishment is adulterated in any of the following respects:

(i) It bears or contains a pesticide chemical, food additive, or color additive, that is ''unsafe'' within the meaning of section 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act or was intentionally subjected to radiation in a manner not permitted under section 409 of said Act; or if it bears or contains any other added poisonous or added deleterious substance which may render it injurious to health or make it unfit for human food; or

(ii) It consists in whole or in part of any filthy, putrid or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food (for example, it was prepared from a poultry carcass or other ingredients exhibiting spoilage characteristics); or it is, or was prepared from, a poultry carcass which would be required to be condemned under subpart K at official establishments; or

(iii) It has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (for example, if insects or vermin are not effectively controlled at the establishment, or insanitary water is used in preparing poultry products for human food); or

(iv) It is, in whole or in part, the product of poultry that died otherwise than by slaughter; or

(v) Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; and

(2) Such adulterated articles are intended to be or are distributed from the establishment while capable of use as human food.

(b) When any such establishment is identified by an inspector as one producing adulterated poultry products which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:

(1) The inspector will informally advise the operator of the establishment concerning the deficiencies found by him and report his findings to the appropriate Regional Director for the Inspection Service. When it is determined by the Regional Director that

any establishment preparing poultry products solely for distribution within any State is producing adulterated poultry products for distribution within such State which would clearly endanger the public health, written notification thereof will be issued to the appropriate State officials, including the Governor of the State and the appropriate Advisory Committee, for effective action under State or local law to prevent such endangering of the public health. Such written notification shall clearly specify the deficiencies deemed to result in the production of adulterated poultry products and shall specify a reasonable time for such action under State or local law.

(2) If effective action is not taken under State or local law within the specified time, written notification shall be issued by the Regional Director to the operator of the establishment, specifying the deficiencies involved and allowing him 10 days to present his views or make the necessary corrections, and notifying him that failure to correct such deficiencies may result in designation of the establishment and operator thereof as subject to the provisions of sections 1 through 4, 6 through 10, and 12 through 22 of the Act as though engaged in commerce.

(3) Thereafter the inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated poultry products, which would clearly endanger the public health, and formal notice of such designation will be issued to the operator of the establishment by the Regional Director.

(c) Poultry products on hand at the time of designation of an establishment under this section are subject to retention or detention, and seizure and condemnation in accordance with §381.145 or subpart U of this part: *Provided*, That poultry products that have been federally inspected and so identified and that have not been further prepared at any nonfederally inspected establishment may be released for distribution if the products appear to be not adulterated or misbranded at the time of such release.

(d) No establishment designated under this section can lawfully prepare any poultry products unless it first obtains inspection or qualifies for exemption under §381.10 of this subpart. All other provisions of the regulations shall apply to establishments designated under this section to the same extent and in the same manner as if they were engaged in commerce, except that the exceptions provided for in §381.222 shall apply to such establishments.

Subpart X [Reserved]

Subpart Y—Nutrition Labeling

SOURCE: 58 FR 675, Jan. 6, 1993, unless otherwise noted.

§381.400 Nutrition labeling of poultry products.

(a) Nutrition labeling must be provided for all poultry products intended for human consumption and offered for sale, except single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401 and are not major cuts of single-ingredient, raw poultry products identified in §381.444, unless the product is exempted under §381.500. Nutrition labeling must be provided for the major cuts of single-ingredient, raw poultry products identified in §381.444, either in accordance with the provisions of §381.409 for nutrition labels, or in accordance with the provisions of §381.445 for point-of-purchase materials, except as exempted under §381.500. For all other products that require nutrition labeling, including ground or chopped poultry products described in §381.401, nutrition labeling must be provided in accordance with the provisions of §381.409, except as exempted under §381.500.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401 and that are not major cuts of single-ingredient, raw poultry products identified in §381.444, either in accordance with the provisions of §381.409 for nutrition labels, or in accordance with

the provisions of §381.445 for point-of-purchase materials.

[75 FR 82166, Dec. 29, 2010]

§ 381.401 Required nutrition labeling of ground or chopped poultry products.

Nutrition labels must be provided for all ground or chopped poultry (kind) with or without added seasonings (including, but not limited to, ground chicken, ground turkey, and (kind) burgers) that are intended for human consumption and offered for sale, in accordance with the provisions of §381.409, except as exempted under §381.500.

[75 FR 82166, Dec. 29, 2010]

§ 381.402 Location of nutrition information.

(a) Nutrition information on a label of a packaged poultry product shall appear on the label's principal display panel or on the information panel, except as provided in paragraphs (b) and (c) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

(c) Poultry products in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition information. In determining the sufficiency of available space for the nutrition information, the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered.

[58 FR 675, Jan. 6, 1993, as amended at 59 FR 40215, Aug. 8, 1994]

§§ 381.403–381.407 [Reserved]

§ 381.408 Labeling of poultry products with number of servings.

The label of any package of a poultry product that bears a representation as to the number of servings contained in such package shall meet the requirements of §381.121(c)(7).

§ 381.409 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term ''serving'' or ''serving size'' means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, the serving size declared on a product label shall be determined from the ''Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply'' (Reference Amount(s)) that appear in §381.412(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, ''for sale only through the _____ program'' (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. However, the Reference Amounts in §381.412(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product ''as packaged'' for all products, except that single-ingredient, raw products that are not ground or chopped poultry products as described in § 381.401 may be declared on the basis of the product ''as consumed.'' For single-ingredient, raw products that are not ground or chopped poultry products described in § 381.401, if data are based on the product ''as consumed,'' the data must be presented in accordance with § 381.445(d). In addition to the required declaration on the basis of ''as packaged'' for products other than single-ingredient, raw products that are not ground or chopped poultry products as described in § 381.401, the declaration may also be made on the basis of ''as consumed,'' provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., chicken wings, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., chicken wings and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare one unit as the serving size if the whole unit can reasonably be consumed at a single eating occasion.

(v) For products that have Reference Amounts of 100 grams (or milliliter) or larger and are individual units within a multi-serving package, if a unit contains more than 150 percent but less than 200 percent of the Reference Amount, the manufacturer may decide whether to declare the individual unit as 1 or 2 servings.

(vi) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., chicken wings and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 381.412(c).

(vii) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza, pan of poultry lasagna), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g., ⅛ quiche, ¼ pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 381.412(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 381.412(c). In expressing the fractional slice, manufacturers shall use ½, ⅓, ¼, ⅕, ⅙, or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole turkey, turkey breast, ground poultry), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., turkey breast and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product determined in § 381.412(c).

(7) For labeling purposes, the term ''common household measure'' or ''common household unit'' means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in ¼- or ⅓-cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 2 tablespoons (tbsp), 1, 1⅓, 1½, or 1⅔ tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in ¼-tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term ''about'' (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., wing, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., chicken wings with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size may be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 381.412(b) and the procedures described in this section, falls exactly half way between two serving sizes (e.g., 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually and that contains less than 200 percent of the applicable Reference Amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving, except for products that have Reference Amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the Reference Amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable Reference Amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2)

through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section. However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced chicken roll. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term ''about'' (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size, the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, a manufacturer may declare ''varied'' for the number of servings per container provided the nutrition information is based on the Reference Amount expressed in ounces. The manufacturer may provide the typical number of servings in parenthesis following the ''varied'' statement (e.g., varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit. The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401, including those that have been previously frozen.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of single-ingredient, raw products that are not ground or chopped poultry products described in § 381.401 and products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) The serving size for meal-type products and main-dish products as defined in §381.413(l) and §381.413 (m) in single-serve containers will be the entire edible content of the package. Serving size for meal-type products and main-dish products in multi-serve containers will be based on the reference amount applicable to the product in §381.412(b) if the product is listed in §381.412(b). Serving size for meal-type products and main-dish products in multi-serve containers that are not listed in §381.412(b) will be based on the reference amount according to §381.412(c), (d), and (e).

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by §381.409(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(14) If a product consists of assortments of poultry products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided,* that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(c) The declaration of nutrition information on the label or in labeling of a poultry product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraph (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraph (d) or (e) of this section.

(1) ''Calories, total,'' ''Total calories,'' or ''Calories'': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, page 25, ''Energy Value of Foods—Basis and Derivation,'' by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA), Agriculture Handbook No. 74 (Slightly revised February 1973), which is incorporated by reference. Table 13 of the ''Energy Value of Foods—Basis and Derivation,'' Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/*

federal__register/code__of__federal__regulations/ibr__locations.html. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference. Pages 9–11, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.); or

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of 21 CFR, or by other means, as appropriate.

(ii) ''Calories from fat'': A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of ''calories from fat'' is not required on products that contain less than 0.5 gram of fat per serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section.

(iii) ''Calories from saturated fat'' or ''Calories from saturated'' (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat per serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) ''Saturated fat'' or ''Saturated'': A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat or cholesterol content, and if ''calories from saturated fat'' is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(A) ''Stearic Acid'' (VOLUNTARY): A statement of the number of grams of stearic acid per serving may be declared voluntarily, except that when a claim is made about stearic acid, label declaration shall be required. Stearic acid content shall be indented under saturated fat and expressed to the nearest 0.5 (½)-gram increment below 5 grams and the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(B) [Reserved]

(ii) ''Polyunsaturated fat'' or ''Polyunsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 381.462(b)(1) for a claim for ''fat free,'' label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) ''Monounsaturated fat'' or ''Monounsaturated'' (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 381.462(b)(1) for a claim for ''fat free,'' label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) ''Cholesterol'': A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as ''less than 5 milligrams.''

(4) ''Sodium'': A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) ''Potassium'' (VOLUNTARY): A statement of the number of milligrams of potassium per serving may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(6) ''Carbohydrate, total'' or ''Total carbohydrate'': A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2 and 3, which is incorporated by reference. Pages 2 and 3, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.).

(i) ''Dietary fiber'': A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement ''Contains less than 1 gram''

or ''less than 1 gram'' may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(A) ''Soluble fiber'' (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) ''Insoluble fiber'' (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) ''Sugars'': A statement of the number of grams of sugars per serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) ''Sugar alcohol'' (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term ''sugar alcohol,'' the name of the specific sugar alcohol (e.g., ''xylitol'') present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) ''Other carbohydrate'' (VOLUNTARY): A statement of the number of grams of other carbohydrate per serving may be declared voluntarily. Other carbohydrate shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) ''Protein'': A statement of the number of grams of protein per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or purported to be for adults and children 4 or more years of age has

a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement ''not a significant source of protein,'' or a listing aligned under the column headed ''Percent Daily Value'' of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be for infants, the statement ''not a significant source of protein'' shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 381.409(h), except when the procedure for a specific food requires another factor.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed ''Percent Daily Value,'' and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be for infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The corrected amount of protein (grams) per serving for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8 in ''Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1990, which is incorporated by reference. Sections 5.4.1, 7.2.1, and 8 of the ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' as published by the Food and Agriculture Organization of the United Nations/World Health Organization, is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700. For products represented or purported to be for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein

value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For products represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on products represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of _____ (listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units
Vitamin C, 60 milligrams
Calcium, 1.0 gram
Iron, 18 milligrams
Vitamin D, 400 International Units
Vitamin E, 30 International Units
Thiamin, 1.5 milligrams
Riboflavin, 1.7 milligrams
Niacin, 20 milligrams

Vitamin B_6, 2.0 milligrams
Folate, 0.4 milligram
Vitamin B_{12}, 6 micrograms
Biotin, 0.3 milligram
Pantothenic acid, 10 milligrams
Phosphorus, 1.0 gram
Iodine, 150 micrograms
Magnesium, 400 milligrams
Zinc, 15 milligrams
Copper, 2.0 milligrams

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., ''Percent Daily Value: Vitamin A 50 (90 percent as *beta*-carotene)''). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat	grams (g)	65
Saturated fatty acids	do	20
Cholesterol	milligrams (mg)	300
Total carbohydrate	grams (g)	300
Fiber	do	25
Sodium	milligrams (mg)	2400
Potassium	do	3500
Protein	grams (g)	50

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, except on products on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on products for infants and children less than 4 years of age as provided for in § 381.500(c), and on products in packages that have a total surface area available to bear labeling of 40 or less square inches as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(3), (d)(5), (d)(7), and (d)(8) of this section shall be in type size no smaller than 8 point. Except for the heading ''Nutrition Facts,'' the information required in paragraphs (d)(4), (d)(6), and (d)(9) of this section and all other information contained within the nutrition label shall be in type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall also be in type no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., ''Nutrition Facts,'' ''Amount Per Serving,'' and ''% Daily Value*''), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., Calories, Total fat, Cholesterol, Sodium, Potassium, Total carbohydrate, and Protein), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate ''Amount Per Serving'' from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it.

(2) The information shall be presented under the identifying heading of ''Nutrition Facts'' which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section.

(3) Information on serving size shall immediately follow the heading. Such information shall include:

(i) ''Serving Size'': A statement of the serving size as specified in paragraph (b)(9) of this section.

(ii) ''Servings Per Container'': The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section or on single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401.

(4) A subheading ''Amount Per Serving'' shall be separated from serving size information by a bar.

(5) Information on calories shall immediately follow the heading ''Amount Per Serving'' and shall be declared in one line, leaving sufficient space between the declaration of ''Calories'' and ''Calories from fat'' to allow clear differentiation, or, if ''Calories from saturated fat'' is declared, in a column with total ''Calories'' at the top, followed by ''Calories from fat'' (indented), and ''Calories from saturated fat'' (indented).

(6) The column heading ''% Daily Value,'' followed by an asterisk (e.g., ''% Daily Value*''), shall be separated from information on calories by a bar. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column heading ''Percent Daily Value,'' ''Percent DV,'' or ''% DV'' may be substituted for ''% Daily Value.''

(7) Except as provided for in paragraph (g) of this section, and except as permitted by § 381.500(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams or ''mg'' for milligrams.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading ''% Daily Value'' established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) or may be listed in two columns, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed ''% Daily Value.''

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of

vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state: Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2,000	2,500
Total fat	Less than	65 g	80 g
Saturated fat ...	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2400 mg	2400 mg
Total carbohydrate.	.....	300 g	375 g
Dietary fiber	.....	25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(7)(ii) of this section, protein shall be listed under dietary fiber, and a value of 50 g shall be inserted on the same line in the column headed ''2,000'' and value of 65 g in the column headed ''2,500.''

(iii) If potassium is declared in the column described in paragraph (d)(7)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (g)(2) of this section may be used within the footnote.

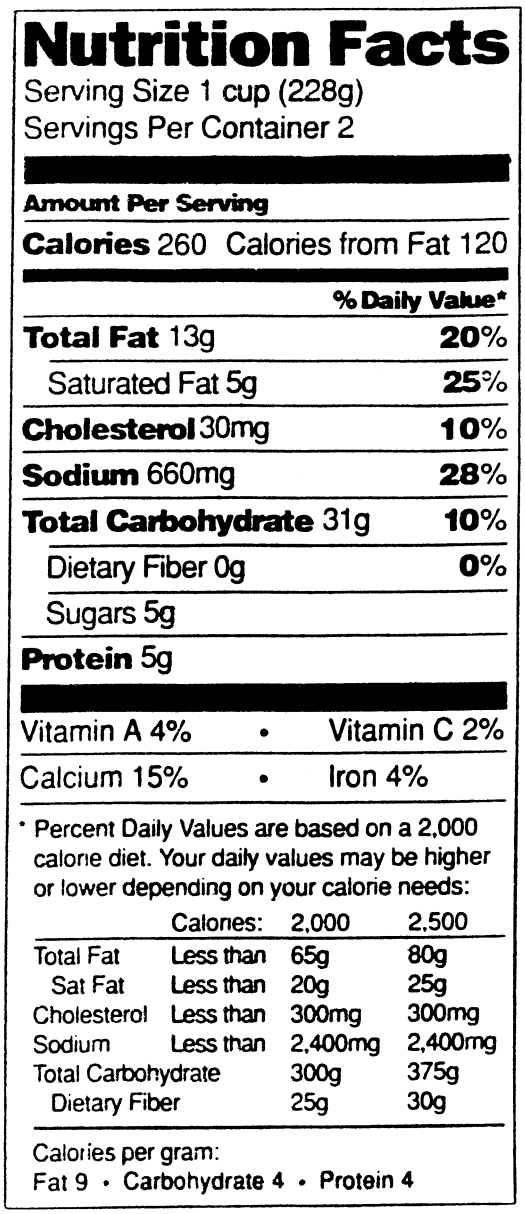
(10) Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (i.e., ''Calories per gram: Fat 9, Carbohydrate 4, Protein 4'') or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of iron is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron, the nutrition label may be presented in a tabular display in which the footnote required by paragraph (d)(9) of the section is given to the far right of the label, and additional vitamins and minerals beyond the four that are required (i.e., vitamin A, vitamin C, calcium, and iron) are arrayed horizontally following declarations of the required vitamins and minerals.

(12) The following sample label illustrates the provisions of paragraph (d) of this section:



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(13)(i) Nutrition labeling on the outer label of packages of poultry products that contain two or more products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type of food (e.g., poultry salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph

(d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the ''Nutrition Facts'' title, and both the quantitative amount by weight (i.e., g/mg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., ''Protein/Proteinas 2 g''). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both ''raw'' and ''cooked'') or for common combinations of foods as provided for in paragraph (b) of this section, or for different units (e.g., per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established (e.g., both infants and children less than 4 years of age) as provided for in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of ''Amount Per Serving,'' there shall be two or more column headings accurately describing the forms of the same product (e.g., ''raw'' and ''roasted''), the combinations of foods, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the Reference Amount in §381.412(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same product, for combinations of foods, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged, but may be on the basis of 'as consumed' for single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401, and according to the label serving size based on the Reference Amount in §381.412(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged, but may be on the basis of 'as consumed' for single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401, and according to the label serving size based on the Reference Amount in §381.412(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

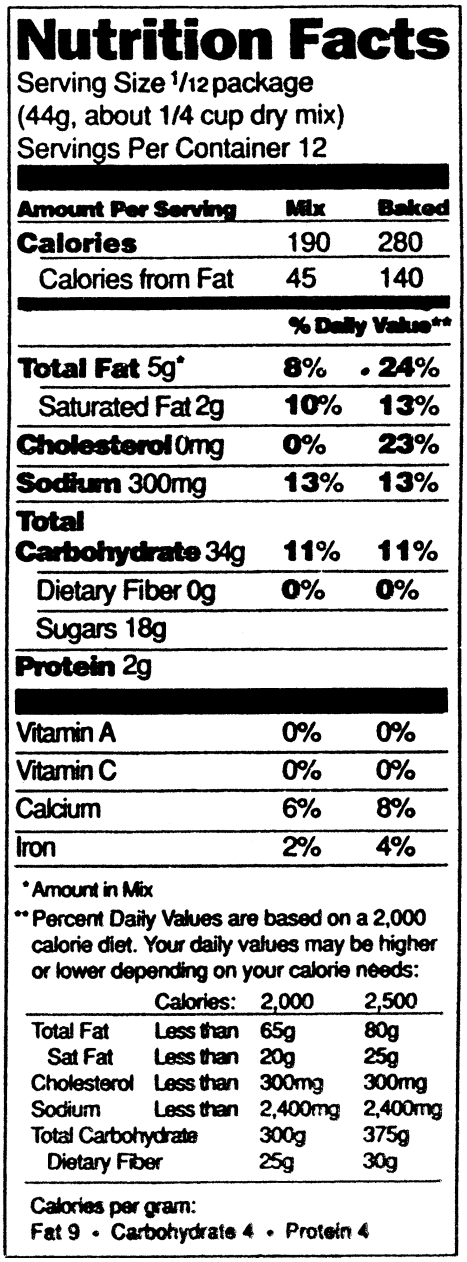
(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged, but may be on the basis of 'as consumed' for single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401, for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which

amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., ½ cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., ''Total fat (2 g)*'') referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading ''% DAILY VALUE'' and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:



Nutrition Facts

Serving Size 1/12 package
(44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	**8%**	**24%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**13%**	**13%**
Total Carbohydrate 34g	**11%**	**11%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(f)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients (i.e., calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that

amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, sodium, and protein;

(ii) Any of the following that are present in more than insignificant amounts: Calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included at the bottom of the nutrition label, ''Not a significant source of _____.'' The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).''

(5) Except as provided for in paragraph (g) of this section and in § 381.500(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required. When the footnote is omitted, an asterisk shall be placed at the bottom of the label followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the heading, a statement that ''DV'' represents ''Daily Value.''

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 381.402(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(ii) When nutrition information is given in a linear display, the nutrition information shall be set off in a box by the use of a hairline. The percent Daily Value is separated from the quantitative amount declaration by the use of parenthesis, and all nutrients, both principal components and subcomponents, are treated similarly. Bolding is required only on the title ''Nutrition Facts'' and is allowed for nutrient names for ''Calories,'' ''Total fat,'' ''Cholesterol,'' ''Sodium,'' ''Total carbohydrate,'' and ''Protein.''

(2) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from fat—Fat cal
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Other carbohydrate—Other carb

(3) Omitting the footnote required in paragraph (d)(9) of this section and placing another asterisk at the bottom of the label followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the

heading, a statement that ''DV'' represents ''Daily Value.''

(4) Presenting the required information on any other label panel.

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the ''Chemistry Laboratory Guidebook,'' or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the ''Official Methods of Analysis'' of the AOAC International, formerly Association of Official Analytical Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 381.409(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The ''Official Methods of Analysis'' is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) if the nutrient content of the composite is greater

than 20 percent in excess of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls above this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference, as provided in §381.445(e) and (f).

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 197, Jan. 3, 1995; 60 FR 10304, Feb. 24, 1995; 69 FR 58802, Oct. 1, 2004; 75 FR 82166, Dec. 29, 2010]

§§ 381.410–381.411 [Reserved]

§ 381.412 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground poultry), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1] [2] [3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g
Plain poultry and poultry sticks, ready-to-serve	55 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1] [2] [3] [4] [5]

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young with poultry).	110 g	n/a
Salad and potato toppers; e.g., poultry bacon bits	7 g	n/a
Bacon; e.g., poultry breakfast strips.	15 g	26 g = bacon. 18 g = breakfast strips
Dried; e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1.	30 g	n/a
Snacks; e.g., poultry snack food sticks	30 g	n/a
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry crumbles, poultry luncheon loaf, potted poultry products, poultry taco filings.	55 g	n/a
Linked poultry sausage products, poultry franks, poultry Polish sausage, smoked or pickled poultry meat, poultry smoked sausage.	55 g	n/a 69 g = uncooked sausage.
Entrees without sauce, poultry cuts, ready to cook poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry.	85 g	114g
Canned poultry, canned chicken, canned [4] turkey	55 g	n/a
Entrees with sauce, turkey and gravy	140 g	n/a
Mixed dishes NOT measurable with a cup; [5] e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche, all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, stuffed vegetables with poultry, poultry kabobs.	140 g (plus 55 g for products toppings)	n/a
Mixed dishes, measurables with a cup; e.g., poultry casserole, macaroni and cheese with poultry, poultry pot pie, poultry spaghetti with sauce, poultry chili, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash, poultry lasagna, poultry-filled pasta.	1 cup	n/a
Salads—pasta or potato, potato salad with poultry, macaroni and poultry salad.	140 g	n/a
Salads—all other, poultry salads, chicken salad, turkey salad	100 g	n/a
Soups—all varieties	245 g	n/a

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1] [2] [3] [4] [5]—Continued

Product category	Reference Amount Ready-to-serve	Reference Amount Ready-to-cook
Major main entree type sauce; e.g., spaghetti sauce with poultry	125 g	n/a
Minor main entree sauce; e.g., pizza sauce with poultry, gravy	¼ cup	n/a
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with poultry.		
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	¼ cup	n/a
Major main entree type sauce	125 g	n/a
Soup	245 g	n/a
Entree measurable with a cup	1 cup	n/a

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.
[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.
[4] If packed or canned in liquid, the Reference Amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed.
[5] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (e.g., poultry lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) For bulk products, the Reference Amount for the combined product shall be the Reference Amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.

(2) For products where the ingredient represented as the main ingredient is one or more discrete units, the Reference Amount for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the Reference Amount for that ingredient as established in paragraph (b) of this section plus proportioned amounts of all minor ingredients.

(3) If the Reference Amounts are in compatible units, they shall be summed (e.g., ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, the weights of the appropriate volumes should be used (e.g., grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 381.413(d), such as a ''low calorie'' version, shall be the

same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parenthesis, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.412 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., turkey as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to

the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of poultry products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the

use of the Reference Amount and/or Product Category.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45198, Sept. 1, 1994; 60 FR 207, Jan. 3, 1995]

§ 381.413 Nutrient content claims; general principles.

(a) This section applies to poultry products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., ''low sodium'' or ''contains 100 calories.''

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., ''high in oat bran''); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., ''healthy, contains 3 grams (g) of fat'').

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in subpart Y of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., ''hi'' or ''lo'').

(c) Information that is required or permitted by § 381.409 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A ''substitute'' product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an ''imitation.''

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., ''not recommended for frying'').

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 381.121(c) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(e)(1) Because the use of a ''free'' or ''low'' claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., ''low sodium chicken noodle soup'').

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered,

formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., ''chicken breast meat, a low sodium food'').

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 381.413, 381.454, 381.456, 381.460, 381.461, 381.462, and 381.480, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 381.500(d)(2).

(h) [Reserved]

(i) Except as provided in § 381.409 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart Y of this part, for the nutrient that the label addresses. Such a claim might be, ''less than 10 g of fat per serving;''

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not ''low'' in or a ''good source'' of the nutrient, such as ''only 200 milligrams (mg) sodium per serving, not a low sodium product.'' The disclaimer must be in easily legible print or type and in a size no less than required by § 381.121(c) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., ''100 calories'' or ''5 grams of fat''), in which case no disclaimer is required.

(4) ''Percent fat free'' claims are not authorized by this paragraph. Such claims shall comply with § 381.462(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as ''relative claims'' and include ''light,'' ''reduced,'' ''less'' (or ''fewer''), and ''more'' claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For ''less'' (or ''fewer'') and ''more'' claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For ''light,'' ''reduced,'' and ''added'' claims, the reference product shall be a similar product, and

(ii)(A) For ''light'' claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than ''light,'' including ''less'' and ''more'' claims, the reference product may be the same as that provided for ''light'' in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a

substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., ''50 percent less fat than 'reference product' '' or ''⅓ fewer calories than 'reference product' ''); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a ''low'' claim for that nutrient.

(k) The term ''modified'' may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., ''modified fat 'product' ''). This statement of identity must be immediately followed by the comparative statement such as ''contains 35 percent less fat than 'reference product' '' The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a ''meal-type'' product will be defined as a product that:

(1) Makes a major contribution to the diet by:

(i) Weighing at least 10 ounces per labeled serving; and

(ii) Containing not less than three 40 gram portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (l)(1)(ii)(A) through (D) of this section, that are in

the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in the form commonly understood to be, a breakfast, lunch, dinner, meal, or entrèe. Such representations may be made by statements, photographs, or vignettes.

(m) For purposes of making a claim, a ''main-dish'' product will be defined as a food that:

(1) Makes a major contribution to the meal by:

(i) Weighing at least 6 ounces per labeled serving; and

(ii) Containing not less than 40 grams of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (m)(1)Iii)(E) of this section.

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (m)(1)(ii)(A) through (D) of this section, that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a main dish (*e.g.*, not a beverage or a dessert). Such representations may be made by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with § 381.409 shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 381.409(h).

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 381.412(b) through (e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 381.412(f) (e.g., ''very low sodium, 35 mg or less per 55 grams'').

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 4(h) of the Act (21 U.S.C. 453(h)(4)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 381.409 may be made on the label or in the labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral.

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such

a claim may be submitted pursuant to §381.469.

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 40215, Aug. 8, 1994; 59 FR 45198, Sept. 1, 1994; 60 FR 208, Jan. 3, 1995; 69 FR 58802, Oct. 1, 2004]

§§ 381.414–381.443 [Reserved]

§ 381.444 Identification of major cuts of poultry products.

The major cuts of single-ingredient, raw poultry products are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 381.445 Nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped products described in § 381.401.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw poultry products identified in §381.444, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under §381.500. If nutrition information is presented on the label, it must be provided in accordance with the provisions of §381.409. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401 and are not major cuts of single-ingredient, raw poultry products identified in §381.444, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of §381.409.

(3) A retailer may provide nutrition information at the point-of-purchase by various methods, such as by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of §381.409 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of §381.409 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in §381.409(c)(8)) and footnote required by §381.409(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in §381.409(f).

(d) The nutrition label data for products covered in paragraphs (a)(1) and (a)(2) must be based on either raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and for products covered in paragraphs (a)(1) and (a)(2) must be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the skinless poultry meat.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference, may be used for nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen. These data may be composite data that reflect different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to class of poultry or other variables, the data must represent the product in the package when such data are contained in the representative

data base. When data are used on labels attached to a product, the data must represent the edible poultry tissues present in the package.

(f) If the nutrition information is provided in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 381.409(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw poultry products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

[58 FR 675, Jan. 6, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 60 FR 209, Jan. 3, 1995; 75 FR 82166, Dec. 29, 2010]

§§ 381.446–381.453 [Reserved]

§ 381.454 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV), established for that nutrient (excluding total carbohydrate) in § 381.409(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *''High'' claims.* (1) The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains a food that meets the definition of ''high'' in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of broccoli in this meal is high in vitamin C'').

(c) *''Good Source'' claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label or in labeling of products, except meal-type products as described in § 381.413(l) and main-dish products as defined in § 317.313(m), provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains a food that meets the definition of ''good source'' in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of sweet potatoes in this meal is a good source of fiber'').

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains ''more'' fiber, and the product is not ''low'' in total fat as defined in § 381.462(b)(2) or, in the case of a meal-type product or in a main-dish product, is not ''low'' in total fat as defined in § 381.462(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., ''contains 12 grams (g) of fat per serving''); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *''More'' claims.* (1) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling

to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber than 'reference product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving'').

(2) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product' ''), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product or in a main-dish product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz'').

[60 FR 210, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§381.455 [Reserved]

§381.456 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the terms ''light'' or ''lite'' to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §381.413; and

(3) The product for which the claim is made is labeled in accordance with §381.409.

(b) *''Light'' claims.* The terms ''light'' or ''lite'' may be used on the label or in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in §381.413(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33⅓ percent) per reference amount customarily consumed compared to an appropriate reference product as described in §381.413(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the

appropriate reference product as described in § 381.413(j)(1); and

(3) As required in § 381.413(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (e.g., ''⅓ fewer calories and 50 percent less fat than the market leader''); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving''); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A ''light'' claim may not be made on a product for which the reference product meets the definition of ''low fat'' and ''low calorie.''

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms ''light'' or ''lite'' without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving'').

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms ''light in sodium'' or ''lite in sodium'' if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that ''light'' or ''lite'' is presented in immediate proximity with ''in sodium'' and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or ''lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving'').

(3) Except for meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), a ''light in sodium'' claim may not be made on a product for which the reference product meets the definition of ''low in sodium.''

(d)(1) The terms ''light'' or ''lite'' may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product meets the definition of:

(A) ''Low in calories'' as defined in § 381.460(b)(3); or

(B) ''Low in fat'' as defined in § 381.462(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether ''light'' is used to mean ''low fat,'' ''low calories,'' or both (e.g., ''Light Delight, a low fat meal''); and

(B) The accompanying statement is no less than one-half the type size of the ''light'' or ''lite'' claim.

(2)(i) The terms ''light in sodium'' or ''lite in sodium'' may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in

§ 381.413(m), provided that the product meets the definition of ''low in sodium'' as defined in § 381.461(b)(5)(i); and

(ii) ''Light'' or ''lite'' and ''in sodium'' are presented in uniform type size, style, color, and prominence.

(3) The terms ''light'' or ''lite'' may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is ''light in sodium'' or ''lite in sodium'' appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

(e) Except as provided in paragraphs (b) through (d) of this section, the terms ''light'' or ''lite'' may not be used to refer to a product that is not reduced in fat by 50 percent, or, if applicable, in calories by ⅓ or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the information (e.g., ''light in color'' or ''light in texture'') so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., ''color'' or ''texture'') is in the same style, color, and at least one-half the type size as the word ''light'' and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word ''light'' has been associated, through common use, with a particular product to reflect a physical or organoleptic attribute to the point where it has become part of the statement of identity, such use of the term ''light'' shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term ''lightly salted'' may be used on a product to which has been added 50 percent less sodium than is normally added to the reference product as described in § 381.413(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not ''low in sodium'' as defined in § 381.461(b)(4), the statement ''not a low sodium food,'' shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 381.413(j)(2).

[60 FR 210, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§§ 381.457–381.459 [Reserved]

§ 381.460 Nutrient content claims for calorie content.

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Calorie content claims.* (1) The terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low calorie,'' ''few calories,'' ''contains a small amount of calories,'' ''low source of calories,'' or ''low in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 318.413(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 120 calories or less per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches.

(4) The terms ''reduced calorie,'' ''reduced in calories,'' ''calorie reduced,'' ''fewer calories,'' ''lower calorie,'' or ''lower in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 318.413(m), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie 'product'—''33 ⅓ percent fewer calories than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 150 to 100 calories per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces

is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(c) *Sugar content claims.* (1) Terms such as ''sugar free,'' ''free of sugar,'' ''no sugar,'' ''zero sugar,'' ''without sugar,'' ''sugarless,'' ''trivial source of sugar,'' ''negligible source of sugar,'' or ''dietarily insignificant source of sugar'' may reasonably be expected to be regarded by consumers as terms that represent that the product contains no sugars or sweeteners, e.g., ''sugar free,'' or ''no sugar,'' as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in §381.409(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of sugars per labeled serving size;

(ii) The product contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sugar,'' ''adds a negligible amount of sugar,'' or ''adds a dietarily insignificant amount of sugar;'' and

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement ''not a reduced calorie product,'' ''not a low calorie product,'' or ''not for weight control.''

(2) The terms ''no added sugar,'' ''without added sugar,'' or ''no sugar added'' may be used only if:

(i) No amount of sugars, as defined in §381.409(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not ''low calorie'' or ''calorie reduced'' (unless the product meets the requirements for a ''low'' or ''reduced calorie'' product) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms ''reduced sugar,'' ''reduced in sugar,'' ''sugar reduced,'' ''less sugar,'' ''lower sugar,'' or ''lower in sugar'' may be used on the label or in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §318.413(m), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate

proximity to the most prominent such claim (e.g., ''this product contains 25 percent less sugar than our regular product''); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has been lowered from 8 g to 6 g per serving'').

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sugar 'product'—

25% less sugar than our regular 'product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz'').

[60 FR 211, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§ 381.461 Nutrient content claims for the sodium content.

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Sodium content claims.* (1) The terms ''sodium free,'' ''free of sodium,'' ''no sodium,'' ''zero sodium,'' ''without sodium,'' ''trivial source of sodium,'' ''negligible source of sodium,'' or ''dietarily insignificant source of sodium'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sodium,'' ''adds a negligible amount of sodium'' or ''adds a dietarily insignificant amount of sodium;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''very low sodium'' or ''very low in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients

per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''low sodium,'' ''low in sodium,'' ''little sodium,'' ''contains a small amount of sodium,'' or ''low source of sodium'' may be used on the label and in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(6) The terms ''reduced sodium,'' ''reduced in sodium,'' ''sodium reduced,'' ''less sodium,'' ''lower sodium,'' or ''lower in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in §381.413(j)(l); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product', 50 percent less sodium than regular 'product' ''); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been lowered from 300 to 150 mg per serving'').

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low sodium.''

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 381.413(j)(l); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product'—30% less sodium per 3 oz than our 'regular product' ''); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz'').

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for ''low sodium.''

(c) The term ''salt'' is not synonymous with ''sodium.'' Salt refers to sodium chloride. However, references to salt content such as ''unsalted,'' ''no salt,'' ''no salt added'' are potentially misleading.

(1) The term ''salt free'' may be used on the label or in labeling of products only if the product is ''sodium free'' as defined in paragraph (b)(1) of this section.

(2) The terms ''unsalted,'' ''without added salt,'' and ''no salt added'' may be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement ''not a sodium free product'' or ''not for control of sodium in the diet'' appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

[60 FR 213, Jan. 3, 1995; 60 FR 5762, Jan. 30, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Fat content claims.* (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''nonfat,'' ''trivial source of fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of fat,'' ''adds a negligible amount of fat,'' or ''adds a dietarily insignificant amount of fat''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or

reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low fat,'' ''low in fat,'' ''contains a small amount of fat,'' ''low source of fat,'' or ''little fat'' may be used on the label and in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced fat,'' ''reduced in fat,'' ''fat reduced,'' ''less fat,'' ''lower fat,'' or ''lower in fat'' may be used on the label or in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced fat—50 percent less fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g to 4 g per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in §381.413(j)(1); and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced fat 'product', 33 percent less fat per 3 oz than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product

per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(6) The term ''_____ percent fat free'' may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for ''low fat'' in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words ''fat free'' are in uniform type size; and

(iii) A ''100 percent fat free'' claim may be made only on products that meet the criteria for ''fat free'' in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for ''_____ percent fat free'' is ''_____ percent lean.''

(c) *Fatty acid content claims.* (1) The terms ''saturated fat free,'' ''free of saturated fat,'' ''no saturated fat,'' ''zero saturated fat,'' ''without saturated fat,'' ''trivial source of saturated fat,'' ''negligible source of saturated fat,'' or ''dietarily insignificant source of saturated fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of saturated fat,'' ''adds a negligible amount of saturated fat,'' or ''adds a dietarily insignificant amount of saturated fat;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low in saturated fat,'' ''low saturated fat,'' ''contains a small amount of saturated fat,'' ''low source of saturated fat,'' or ''a little saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced saturated fat,'' ''reduced in saturated fat,'' ''saturated fat reduced,'' ''less saturated fat,'' ''lower saturated fat,'' or ''lower in saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat reduced from 3 g to 1.5 g per serving'').

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product', 50 percent less saturated fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz'').

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(d) *Cholesterol content claims.* (1) The terms ''cholesterol free,'' ''free of cholesterol,'' ''zero cholesterol,'' ''without cholesterol,'' ''no cholesterol,'' ''trivial source of cholesterol,'' ''negligible source of cholesterol,'' or ''dietarily insignificant source of cholesterol'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of cholesterol,'' ''adds a negligible amount of cholesterol,'' or ''adds a dietarily insignificant amount of cholesterol'';

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d)

that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''cholesterol free 'product', contains 100 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''contains no cholesterol compared with 30 mg in one serving of 'reference product' '').

(2) The terms ''low in cholesterol,'' ''low cholesterol,'' ''contains a small amount of cholesterol,'' ''low source of cholesterol,'' or ''little cholesterol'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''low cholesterol 'product', contains 85 percent less cholesterol than our regular 'product'''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 30 mg to 5 mg per serving'').

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced cholesterol,'' ''reduced in cholesterol,'' ''cholesterol reduced,'' ''less cholesterol,'' ''lower cholesterol,'' or ''lower in cholesterol'' may be used on the label or in labeling of products or products that substitute

for those products as specified in §381.413(d), excluding meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in §381.413(j)(1) and for which it substitutes as described in §381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 55 mg to 30 mg per serving'').

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in §381.413(j)(1) and for which it substitutes as described in §381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25% less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(e) *''Lean'' and ''Extra Lean'' claims.* (1) The term ''lean'' may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m).

(2) The term ''extra lean'' may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m).

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped poultry products described in §381.401 when the product does not meet the criteria for ''low fat,'' defined in §381.462(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and

on the same color background, as the statement of the lean percentage.

[60 FR 214, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004; 75 FR 82167, Dec. 29, 2010]

§ 381.463 Nutrient content claims for "healthy."

(a) The term ''healthy,'' or any other derivative of the term ''health,'' may be used on the labeling of any poultry product, provided that the product is labeled in accordance with § 381.409 and § 381.413.

(b)(1) The product shall meet the requirements for ''low fat'' and ''low saturated fat,'' as defined in § 381.462, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for ''extra lean'' in § 381.462.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 381.413(m), and meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for ''extra lean'' in § 381.462.

(3) The product shall not contain more than 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 381.413(m), and meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 600 mg of sodium per labeled serving size;[1] and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 381.409 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A main-dish product, as defined in § 381.413(m), and including meal-type products that weigh less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in § 381.413(l), shall meet the level for three of the nutrients per labeled serving size.

[59 FR 24228, May 10, 1994, as amended at 60 FR 217, Jan. 3, 1995; 63 FR 7281, Feb. 13, 1998; 64 FR 72492, Dec. 28, 1999; 68 FR 463, Jan. 6, 2003; 69 FR 58803, Oct. 1, 2004; 71 FR 1686, Jan. 11, 2006]

§§ 381.464–381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

[1] This regulation previously provided that, after January 1, 2006, individual poultry products bearing the claim ''healthy'' (or any derivative of the term ''health'') must contain no more than 360 mg of sodium and that meal-type products bearing the claim ''healthy'' (or any other derivative of the term ''health'') must contain no more than 600 mg of sodium. Implementation of these sodium level requirements for products bearing the claim ''healthy'' (or any derivative of the term ''health'') has been deferred indefinitely due to technological barriers and consumer preferences.

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement

shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 381.409(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish

in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart Y of part 381).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the

meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the FEDERAL REGISTER a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within

the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the FEDERAL REGISTER seeking a comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the

complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a notice informing the public that the implied nutrient content claim has been approved for use.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993, as amended at 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995]

§§ 381.470–381.479 [Reserved]

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 381.409 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., ''Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s).''

(c) *''Low calorie'' foods.* A product purporting to be ''low calorie'' must comply with the criteria set forth for such foods in § 381.460.

(d) *''Reduced calorie'' foods and other comparative claims.* A product purporting to be ''reduced calorie'' or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 387.460(b) (4) and (5).

(e) *''Label terms suggesting usefulness as low calorie or reduced calorie foods''.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as ''diet,'' ''dietetic,'' ''artificially sweetened,'' or ''sweetened with nonnutritive sweetener'' only if the claim is not false or misleading, and the product is labeled ''low calorie'' or ''reduced calorie'' or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term ''diet'' that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., ''for low sodium diets.''

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a

regulation governing the use of such terms on foods.

(f) ''Sugar free'' and ''no added sugar''. Criteria for the use of the terms ''sugar free'' and ''no added sugar'' are provided for in § 381.460(c).

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 60 FR 217, Jan. 3, 1995]

§§ 381.481–381.499 [Reserved]

§ 381.500 Exemption from nutrition labeling.

(a) The following poultry products are exempt from nutrition labeling:

(1) Food products produced by small businesses other than the major cuts of single-ingredient, raw poultry products identified in § 381.444 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in § 381.401 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with § 381.462(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

(i) A food product, for purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility, including a single retail store, or multi-plant company/firm, including a multi-retail store operation that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to ready-to-eat ground or chopped poultry products described in § 381.401 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under (a)(1);

(ii) Multi-ingredient products (e.g. sausage) processed at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to multi-ingredient ground or chopped poultry products described in § 381.401 that are processed at a retail establishment, unless the establishment qualifies for an exemption under (a)(1); and

(iii) Products that are ground or chopped at an individual customer's request.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling as provided in paragraph (c)(2) of this section, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol.

(2) Foods represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling except that:

(i) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;

(ii) Nutrient names and quantitative amounts by weight shall be presented in two separate columns;

(iii) The heading ''Percent Daily Value'' required in § 381.409(d)(6) shall be placed immediately below the quantitative information by weight for protein;

(iv) The percent of the Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading ''Percent Daily Value''; and

(v) Such labeling shall not include the footnote specified in § 381.409(d)(9).

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., ''For nutrition information call 1–800–123–4567'').

(2) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in a type size no smaller than 6 point or all upper case type of 1/16-inch minimum height, except that individual serving-size packages of poultry products that have a total area available to bear labeling of 3 square inches or less may provide all required information in a type size no smaller than 1/32-inch minimum height.

[58 FR 675, Jan. 6, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995; 75 FR 82167, Dec. 29, 2010; 76 FR 76891, Dec. 9, 2011]

Subpart Z—Selected Establishments; Cooperative Program for Interstate Shipment of Poultry Products

SOURCE: 76 FR 24756, May 2, 2011, unless otherwise noted.

§ 381.511 Definitions.

Cooperative interstate shipment program. A cooperative poultry products inspection program described in § 381.187 of this part.

Cooperative State poultry products inspection program. A cooperative State-Federal poultry products inspection program described in § 381.185 of this part.

Designated personnel. State inspection personnel that have been trained in the enforcement of the Act and any additional State program requirements in order to provide inspection services to selected establishments.

Interstate commerce. ''Interstate commerce'' has the same meaning as ''commerce'' under § 381.1 of this part.

Selected establishment. An establishment operating under a State cooperative poultry products inspection program that has been selected by the Administrator, in coordination with the State where the establishment is located, to participate in a cooperative interstate shipment program.

§ 381.512 Purpose.

This subpart Z prescribes the conditions under which States that administer cooperative State poultry products inspection programs and establishments that operate under such programs may participate in a cooperative interstate shipment program.

§ 381.513 Requirements for establishments; ineligible establishments.

(a) An establishment that operates under a cooperative State poultry products inspection program may apply to participate in a cooperative interstate shipment program under this subpart if:

(1) The establishment employs on average no more than 25 employees based on the standards described in paragraph (b) of this section, or

(2) The establishment employed more than 25 employees but fewer than 35 employees as of June 18, 2008. If selected to participate in a cooperative interstate shipment program, an establishment under this paragraph must employ on average no more than 25 employees as of July 1, 2014, or it must transition to become an official establishment as provided in § 381.521 of this subpart.

(b) An establishment that has 25 or fewer employees based on the following standards is considered to have 25 or fewer employees on average for purposes of this subpart.

(1) All individuals, both supervisory and non-supervisory, employed by the establishment on a full-time, part-time, or temporary basis whose duties involve handling the poultry products prepared by the establishment are counted when calculating the total number of employees.

(2) All individuals employed by the establishment from a temporary employee agency, professional employee organization, or leasing concern whose duties involve handling the poultry products prepared by the establishment are counted when calculating the total number of employees.

(3) The average number of employees is calculated for each of the pay periods for the preceding 12 calendar months.

(4) Part-time and temporary employees are counted the same as full-time employees.

(5) If the establishment has not been in business for 12 months, the average number of employees is calculated for each of the pay periods in which the establishment has been in business.

(6) Volunteers who receive no compensation are not considered employees unless their duties involve handling the poultry products prepared by the establishment.

(7) The total number of employees can never exceed 35 individuals at any given time, regardless of the average number of employees.

(c) The following establishments are ineligible to participate in a cooperative interstate shipment program:

(1) Establishments that employ more than 25 employees on average (except as provided under paragraph (a)(2) of this section);

(2) Establishments operating under a Federal-State program as provided in § 381.186 of this part as of June 18, 2008;

(3) Official establishments;

(4) Establishments that were official establishments as of June 18, 2008, but that were re-organized on a later date by the person that controlled the establishment as of June 18, 2008;

(5) Establishments operating under a cooperative State poultry products inspection program that employed more than 35 employees as of June 18, 2008, that were reorganized on a later date by the person that controlled the establishment as of June 18, 2008;

(6) Establishments that are the subject of a transition under § 381.521 of this subpart;

(7) Establishments that are in violation of the Act;

(8) Establishments located in States without a cooperative State poultry products inspection program; and

(9) Establishments located in a State whose agreement for a cooperative interstate shipment program was terminated by the Administrator as provided in § 381.187(d) of this part.

(d) An establishment that meets the conditions in paragraph (a) of this section and that is not an ineligible establishment under paragraph (c) of this section may apply for selection into a cooperative interstate shipment program through the State in which the establishment is located.

[76 FR 24756, May 2, 2011, as amended at 76 FR 81360, Dec. 28, 2011]

§ 381.514 State request for cooperative agreement.

(a) State participation in a cooperative interstate shipment program under this subpart is limited to States that have implemented cooperative

State poultry products inspection programs.

(b) To request an agreement for a cooperative interstate shipment program under this subpart, a State must submit a written request to the Administrator through the FSIS District Office for the FSIS District in which the State is located. In the request the State must:

(1) Identify establishments in the State that have requested to be selected for the program that the State recommends for initial selection into the program, if any;

(2) Demonstrate that the State is able to provide the necessary inspection services to selected establishments in the State and conduct any related activities that would be required under a cooperative interstate shipment program established under this subpart; and

(3) Agree that, if the State enters into an agreement with FSIS for a cooperative interstate shipment program, the State will:

(i) Provide FSIS with access to the results of all laboratory analyses conducted on product samples from selected establishments in the State;

(ii) Notify the selected establishment coordinator for the State of the results of any laboratory analyses that indicate that a product prepared in a selected establishment may be adulterated or may otherwise present a food safety concern; and

(iii) When necessary, cooperate with FSIS to transition selected establishments in the State that have been deselected from a cooperative interstate shipment program to become official establishments.

(c) If the Administrator determines that a State that has submitted a request to participate in a cooperative interstate shipment program qualifies to enter into a cooperative agreement for such a program, the Administrator and the State will sign a cooperative agreement that sets forth the terms and conditions under which each party will cooperate to provide inspection services to selected establishments located in the State.

(d) After the Administrator and a State have signed an agreement for a cooperative interstate shipment program as provided in paragraph (c) of this section, the Administrator will:

(1) Appoint an FSIS employee as the FSIS selected establishment coordinator for the State and

(2) Coordinate with the State to select establishments to participate in the program as provided in § 381.515(b) of this subpart.

§ 381.515 Establishment selection; official number for selected establishments.

(a) An establishment operating under a cooperative State poultry products inspection program will qualify for selection into a cooperative interstate shipment program if the establishment:

(1) Has submitted a request to the State to be selected for the program;

(2) Has the appropriate number of employees under § 381.513(a) of this subpart;

(3) Is not ineligible to participate in a cooperative interstate shipment program under § 381.513(c) of this subpart;

(4) Is in compliance with all requirements under the cooperative State poultry products inspection program; and

(5) Is in compliance with all requirements under the Act and the implementing regulations in this chapter.

(b) To participate in a cooperative interstate shipment program, an establishment that meets the conditions in paragraph (a) of this section must be selected by the Administrator, in coordination with the State where the establishment is located.

(c) If an establishment is selected to participate in a cooperative interstate shipment program as provided in paragraph (b) of this section, the State is to assign the establishment an official number that reflects the establishment's participation in the cooperative interstate shipment program and advise the FSIS selected establishment coordinator for the State of the official number assigned to each selected establishment in the State. The official numbers assigned to every selected establishment must contain a suffix, e.g., ''SE,'' that identifies the establishment as a selected establishment; that includes the letter ''P,'' which identifies

the establishment as a poultry establishment; and that identifies the State, e.g., ''SEPND,'' for ''selected establishment poultry North Dakota.''

(d) Failure of a State to comply with paragraph (c) of this section will disqualify the State from participation in the cooperative interstate shipment program.

§ 381.516 Commencement of a cooperative interstate shipment program; inspection by designated personnel and official mark.

(a) A cooperative interstate shipment program will commence when the Administrator, in coordination with the State, has selected establishments in the State to participate in the program.

(b) Inspection services for selected establishments participating in a cooperative interstate shipment program must be provided by designated personnel, who will be under the direct supervision of a State employee.

(c) Poultry products processed in a selected establishment and inspected and passed by designated State personnel must bear an official Federal mark, stamp, tag, or label of inspection in the appropriate form prescribed in subpart M of this part that includes the information specified in § 381.515(c) of this subpart.

(d) Poultry products processed in a selected establishment that comply with the conditions in paragraph (c) of this section may be distributed in interstate commerce.

§ 381.517 Federal oversight of a cooperative interstate shipment program.

(a) The FSIS selected establishment coordinator for a State that has entered into an agreement for a cooperative interstate shipment program will visit each selected establishment in the State on a regular basis to verify that the establishment is operating in a manner that is consistent with the Act and the implementing regulations in this chapter. The frequency with which the SEC will visit selected establishments under the SEC's jurisdiction will be based on factors that include, but are not limited to, the complexity of the operations conducted at the selected establishment, the establishment's schedule of operations, and the establishment's performance under the cooperative interstate shipment program. If necessary, the selected establishment coordinator, in consultation with the District Manager that covers the State, may designate qualified FSIS personnel to visit a selected establishment on behalf of the selected establishment coordinator.

(b) The selected establishment coordinator, in coordination with the State, will verify that selected establishments in the State are receiving the necessary inspection services from designated personnel, and that these establishments are eligible, and remain eligible, to participate in a cooperative interstate shipment program. The selected establishment coordinator's verification activities may include:

(1) Verifying that each selected establishment employs, and continues to employ, 25 or fewer employees, on average, as required under § 381.513(a) of this part, unless the establishment is transitioning to become an official establishment;

(2) Verifying that the designated personnel are providing inspection services to selected establishments in a manner that complies with the Act and the implementing regulations in this chapter;

(3) Verifying that that the State staffing levels for each selected establishments are appropriate to carry out the required inspection activities; and

(4) Assessing each selected establishment's compliance with the Act and implementing regulations in this chapter.

(c) If the selected establishment coordinator determines that designated personnel are providing inspection services to selected establishments in the State in a manner that is inconsistent with the Acts and the implementing regulations in this chapter, the Administrator will provide an opportunity for the State to develop and implement a corrective action plan to address inspection deficiencies identified by the selected establishment coordinator. If the State fails to develop a corrective action plan, or the selected establishment coordinator for

the State determines that the corrective action plan is inadequate, the Administrator will terminate the agreement for the cooperative interstate shipment program as provided in § 381.187(d) of this part.

§ 381.518 Quarterly reports.

(a) The selected establishment coordinator will prepare a report on a quarterly basis that describes the status of each selected establishment under his or her jurisdiction.

(b) The quarterly report required in paragraph (a) of this section will:

(1) Include the selected establishment coordinator's assessment of the performance of the designated personnel in conducting inspection activities at selected establishments and

(2) Identify those selected establishment that the selected establishment coordinator has verified are in compliance with the Act and implementing regulations in this chapter, those that have been deselected under § 381.520 of this subpart, and those that are transitioning to become official establishments under § 381.521 of this subpart.

(c) The selected establishment coordinator is to submit the quarterly report to the Administrator through the District Manager for the State where the selected establishments identified in the report are located.

§ 381.519 Enforcement authority.

(a) To facilitate oversight and enforcement of this subpart, selected establishments operating under a cooperative interstate shipment program must, upon request, give the FSIS selected establishment coordinator or other FSIS officials access to all establishment records required under the Act and the implementing regulations in this chapter. The Administrator may deselect any selected establishment that refuses to comply with this paragraph.

(b) Selected establishment coordinators may initiate any appropriate enforcement action provided for in part 500 of this chapter if they determine that a selected establishment under their jurisdiction is operating in manner that is inconsistent with the Act and the implementing regulations in this chapter. Selected establishments participating in a cooperative interstate shipment program are subject to the notification and appeal procedures set out in part 500 of this chapter.

(c) If inspection at a selected establishment is suspended for any of the reasons specified in § 500.3 or § 500.4 of this chapter, FSIS will:

(1) Provide an opportunity for the establishment to implement corrective actions and remain in the cooperative interstate shipment program, or

(2) Move to deselect the establishment as provided in § 381.520 of this subpart.

(d) The decision to deselect a selected establishment under a suspension will be made on a case-by-case basis. In making this decision, FSIS, in consultation with the State where the selected establishment is located, will consider, among other factors:

(1) The non-compliance that led to the suspension;

(2) The selected establishment's compliance history; and

(3) The corrective actions proposed by the selected establishment.

§ 381.520 Deselection of ineligible establishments.

(a) The Administrator will deselect a selected establishment that becomes ineligible to participate in a cooperative interstate shipment program for any reason listed under § 381.513(c) of this subpart.

(b) An establishment that has been deselected must transition to become an official establishment as provided in § 381.521 of this subpart.

§ 381.521 Transition to official establishment.

(a) If an establishment is deselected from a cooperative interstate shipment program as provided in § 381.520 of this subpart, FSIS, in coordination with the State where the establishment is located, will develop and implement a plan to transition the establishment to become an official establishment. Except that an establishment that was deselected from a cooperative interstate shipment program because it is located in a State whose agreement for such a program was terminated may either transition to become an official

establishment or transition to become a State-inspected establishment under the cooperative State poultry products inspection program.

(b) An establishment that has been deselected from a cooperative interstate shipment program and successfully transitioned to become an official establishment may withdraw from the Federal inspection program and resume operations under the cooperative State poultry products inspection program after operating as an official establishment in full compliance with the Act for a year.

§ 381.522 Transition grants.

(a) Transition grants are funds that a State participating in a cooperative interstate shipment program under this subpart may apply for to reimburse selected establishments in the State for the cost to train one individual in the seven HACCP principles for meat or poultry processing as required under § 417.7 of this chapter and associated training in the development of sanitation standard operating procedures required under part 416 of this chapter.

(b) A State participating in a cooperative interstate shipment program that receives a transition grant must use grant funds to reimburse the training costs of one employee per each selected establishment in the State. Any other use of such funds is prohibited.

§ 381.523 Separation of operations.

A selected establishment may conduct operations under the cooperative State poultry products inspection program if the establishment implements and maintains written procedures for complete physical separation of product and process for each operation by time or space.

§ 381.524 Voluntary withdrawal.

A selected establishment that is in full compliance with the requirements in this part may voluntarily end its participation in a cooperative interstate shipment program and operate under the cooperative State poultry products inspection program. Establishments that voluntarily end their participation in the cooperative may re-apply for the program after operating under the cooperative State poultry products inspection program for one year.

SUBCHAPTERS B–C [RESERVED]

SUBCHAPTER D—FOOD SAFETY AND INSPECTION SERVICE ADMINISTRATIVE PROVISIONS

PART 390—FREEDOM OF INFORMATION AND PUBLIC INFORMATION

Sec.

AUTHORITY: 5 U.S.C. 301, 552; 21 U.S.C. 451–471, 601–695; 7 CFR 1.3, 2.7.

SOURCE: 64 FR 43903, Aug. 12, 1999, unless otherwise noted.

§ 390.1 Scope and purpose.

This part is issued pursuant to the Freedom of Information Act (FOIA) as amended (5 U.S.C. 552), and in accordance with the directives of the Department of Agriculture regulations in part 1, subpart A, of Title 7. The availability of records, including electronic records created on or after November 1, 1996, of the Food Safety and Inspection Service (FSIS), and the procedures by which the public may request such information, will be governed by the FOIA and by the Department regulations as implemented and supplemented by the regulations in this part.

§ 390.2 Published materials.

FSIS rules and regulations relating to its regulatory responsibilities and administrative procedures are published and made available to the public in the FEDERAL REGISTER and codified in chapter III, title 9, of the Code of Federal Regulations. FSIS also issues numerous publications relating to Agency programs, which implement the laws listed in the Delegation of Authority, 7 CFR 2.15(a). Most of these publications are available free from the USDA Publications Division, Office of Governmental and Public Affairs, or at established rates from the Superintendent of Documents, U.S. Government Printing Office, Washington, 20402–9328.

§ 390.3 Indexes, reference guide, and handbook.

(a) Pursuant to the regulations in 7 CFR 1.4(c), FSIS will maintain and make available for public inspection and copying an index providing identifying information regarding the materials required to be published or made available under the Freedom of Information Act (5 U.S.C. 552(a)(2)). The Agency will make the index available by computer telecommunications by December 31, 1999. Quarterly publication of the index is unnecessary and impractical, since the material is voluminous and does not change often enough to justify the expense of quarterly publication. The Agency will provide copies of any index, upon request, at a cost not to exceed direct cost of duplication.

(b) FSIS is responsible for preparing reference material or a guide for requesting records or information from the Agency. This guide also will include an index of all major information systems and a description of major information and record locator systems.

(c) FSIS will prepare a handbook for obtaining information from the Agency. The handbook will be available on paper and through electronic means, and will discuss how the public can use it to access Agency FOIA annual reports. Similarly, the annual reports will refer to the handbook and how to obtain it.

§ 390.4 Facilities for inspection and copying.

Facilities for public inspection and copying of the material described in §§ 390.2 and 390.3 of this part will be provided by FSIS pursuant to 7 CFR 1.5(a) in a reading area, on business days between the hours of 8:30 a.m. and 4:30 p.m., upon request to the Freedom of

Information Coordinator or designee at the following address:

Freedom of Information Act Coordinator (FOIA), Food Safety and Inspection Service, Department of Agriculture, Washington, DC 20250–3700

§ 390.5 Request for records.

(a) The FOIA Coordinator of FSIS is authorized to receive requests and to exercise authority under 7 CFR 1.3(a) to—

(1) Make determinations to grant or deny such requests,

(2) Extend the 20-day deadline,

(3) Make discretionary releases of exempt records, except where disclosure is specifically prohibited by Executive Order, statute, and applicable regulations,

(4) Consider expedited processing when appropriate,

(5) Make determinations regarding the charging of fees pursuant to the established schedule, and

(6) Determine the applicability of 7 CFR 1.5 to requests for records.

(b) Requests for FSIS records or information will be made in writing in accordance with 7 CFR 1.5 and submitted to the FSIS Freedom of Information Act Coordinator at the following address:

Freedom of Information Act Coordinator (FOIA Request), Food Safety and Inspection Service, Department of Agriculture, Washington, DC 20250–3700

The submitter will identify each record with reasonable specificity as prescribed in 7 CFR 1.3. All requests to inspect or obtain copies of any record or to obtain a fee waiver must be submitted in writing.

(c) In exercising authority under 7 CFR 1.3(a)(3) to grant and deny requests, the Coordinator or designee will comply with subsection (b) of the Freedom of Information Act (5 U.S.C. 552(b)), as amended, which requires that any reasonably segregated portion of a document will be provided to a person requesting the document after deletion of any portions within the scope of the request for which an exemption is being claimed under the Act. Therefore, unless the disclosable and nondisclosable portions are so inextricably linked that it is not reasonably possible to separate them, the document will be released with the nondisclosable portions deleted. The Coordinator or designee may exercise discretion as limited by 7 CFR 1.15 to release the entire document or make only a minimum number of deletions. If portions of a document in electronic format have been redacted, the Agency must indicate, on the released portion of the document, the amount of information that has been deleted from a record, unless that indication would harm an interest protected by an applicable exemption.

§ 390.6 Fee schedule.

Department regulations provide for a schedule of reasonable standard charges for document search and duplication. See 7 CFR 1.17. Fees to be charged are in 7 CFR part 1, subpart A, appendix A.

§ 390.7 Appeals.

(a) If the request for information or for a waiver of search or duplication is denied, in whole or in part, the FOIA Coordinator or designee will explain in the letter of response the grounds for any denial of access and offer the requester an opportunity to file an administrative appeal, pursuant to 7 CFR 1.3(a)(4). The appeal should be filed in writing within 45 days of the date of denial (departmental regulations, 7 CFR 1.14) and addressed as follows:

Administrator, Food Safety and Inspection Service (FOIA Appeals), Department of Agriculture, Washington, DC 20250–3700

(b) The FSIS Administrator is authorized under 7 CFR 1.3(a)(4) to extend the 20-day deadline, make discretionary releases, and make determinations regarding the charging of fees.

§ 390.8 Agency response to requests.

(a) The response to Freedom of Information requests and appeals by officials named in §§ 390.5 and 390.7 of this part shall be governed by and made in accordance with 7 CFR 1.7 and the regulations in this part.

(b) If requests for records and information are received by field offices, the field office will immediately notify the FOIA Coordinator or designee by telephone and transmit the request to the FOIA office. In rare instances, the

FOIA Coordinator or designee will authorize a release of the requested records to the field office receiving the request. The request will be considered as having been received on the date of arrival in the office of the Coordinator or designee. Any person whose request for records has been granted may inspect and copy the records (or copies) at the office listed in § 390.4 of this part in accordance with the provisions of that section and with § 390.6. Copies also may be obtained by mail.

§ 390.9 Communications with State and other Federal government agencies.

(a) The Administrator of the Food Safety and Inspection Service (FSIS), or designee, may authorize the disclosure of distribution lists (records that show where and when product was shipped) obtained from a firm recalling products, or incorporated into agency-prepared records, to State and other Federal government agencies to verify the removal of the recalled product, provided that:

(1) The State agency has provided both a written statement establishing its authority to protect confidential distribution lists from public disclosure and a written commitment not to disclose any information provided by FSIS, without the written permission of the submitter of the information or written confirmation by FSIS that the information no longer has confidential status. Federal government agencies must provide a written commitment not to disclose the information and to refer any request for distribution lists to FSIS for response; and

(2) The Administrator of FSIS or designee determines that disclosure would be in the interest of public health.

(b) This provision does not authorize the disclosure to State or other Federal government agencies of trade secret information, unless otherwise provided by law or pursuant to an express written authorization provided by the submitter of the information.

(c) Information disclosed under this section is not a disclosure of information to the public. Disclosures made under this section do not waive any FOIA exemption protection.

[67 FR 20013, Apr. 24, 2002]

§ 390.10 Availability of Lists of Retail Consignees during Meat or Poultry Product Recalls.

The Administrator of the Food Safety and Inspection Service will make publicly available the names and locations of retail consignees of recalled meat or poultry products that the Agency compiles in connection with a recall where there is a reasonable probability that the use of the product could cause serious adverse health consequences or death.

[73 FR 40948, July 17, 2008]

PART 391—FEES AND CHARGES FOR INSPECTION SERVICES AND LABORATORY ACCREDITATION

Sec.

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 1622, 1627 and 2219a; 21 U.S.C. 451 *et seq.;* 21 U.S.C. 601–695; 7 CFR 2.18 and 2.53.

§ 391.1 Scope and purpose.

Fees shall be charged by the Agency for certain specified inspection services provided on a holiday, on an overtime basis, and/or which are voluntary inspection services.

[54 FR 6390, Feb. 10, 1989]

§ 391.2 Basetime rate.

(a) For each calendar year, FSIS will calculate the basetime rate for inspection services, per hour per program employee, provided pursuant to §§ 350.7, 351.8, 351.9, 352.5, 354.101, 355.12, and 362.5 of this chapter, using the following formula: The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

(b) FSIS will calculate the benefits, travel and operating, overhead, and allowance for bad debt rate components of the basetime rate, using the following formulas:

(1) *Benefits rate.* The quotient of dividing the previous fiscal year's direct benefits costs by the previous fiscal year's total hours (regular, overtime, and holiday), plus the quotient multiplied by the calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan basic and matching contributions.

(2) *Travel and operating rate.* The quotient of dividing the previous fiscal year's total direct travel and operating costs by the previous fiscal year's total hours (regular, overtime, and holiday), plus the quotient multiplied by the calendar year's percentage of inflation.

(3) *Overhead rate.* The quotient of dividing the previous fiscal year's indirect costs plus the previous fiscal year's information technology (IT) costs in the Public Health Data Communication Infrastructure System Fund plus the previous fiscal year's Office of Management Program cost in the Reimbursable and Voluntary Funds plus the provision for the operating balance less any Greenbook costs (i.e., costs of USDA support services prorated to the service component for which the fees are charged) that are not related to food inspection, by the previous fiscal year's total hours (regular, overtime, and holiday) worked across all funds, plus the quotient multiplied by the calendar year's percentage of inflation.

(4) *Allowance for bad debt rate.* Previous fiscal year's allowance for bad debt (for example, debt owed that is not paid in full by plants and establishments that declare bankruptcy) divided by the previous fiscal year's total hours (regular, overtime, and holiday) worked.

(c) The calendar year's cost of living increases and percentage of inflation factors used in the formulas in this section are based on the Office of Management and Budget's Presidential Economic Assumptions.

[76 FR 20227, Apr. 12, 2011]

§ 391.3 Overtime and holiday rates.

For each calendar year, FSIS will calculate the overtime and holiday rates, per hour per program employee, provided pursuant to §§ 307.5, 350.7, 351.8, 351.9, 352.5, 354.101, 355.12, 362.5, and 381.38 of this chapter, using the following formulas:

(a) *Overtime rate.* The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, multiplied by 1.5, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

(b) *Holiday rate.* The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, multiplied by 2, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

(c) FSIS will calculate the benefits rate, the travel and operating rate, the overhead rate, and the allowance for bad debt rate using the formulas set forth in § 391.2(b), and the cost of living increases and percentage of inflation factors set forth in § 391.2(c).

[76 FR 20227, Apr. 12, 2011]

§ 391.4 Laboratory services rate.

(a) For each calendar year, FSIS will calculate the laboratory services rate, per hour per program employee, provided pursuant to §§ 350.7, 351.9, 352.5, 354.101, 355.12, and 362.5 of this chapter, using the following formula: The quotient of dividing the Office of Public Health Science (OPHS) previous fiscal year's regular direct pay by OPHS previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage cost of living increase, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

(b) FSIS will calculate the benefits rate, the travel and operating rate, the overhead rate, and the allowance for bad debt rate using the formulas set forth in § 391.2(b), and the cost of living increases and percentage of inflation factors set forth in § 391.2(c).

[76 FR 20228, Apr. 12, 2011]

§ 391.5 Laboratory accreditation fees.

(a) The annual fee for the accreditation and maintenance of accreditation provided pursuant to § 439.5 of this chapter shall be $5,000 for the first analyte class, $2,900 for the second analyte class, and $2,100 for each additional analyte class.

(b) Laboratories that request special onsite inspections shall pay FSIS the actual cost of reasonable travel and other expenses necessary to perform the unscheduled or non-routine onsite inspections.

[58 FR 65269, Dec. 13, 1993, as amended at 59 FR 66449, Dec. 27, 1994; 64 FR 19868, Apr. 23, 1999; 71 FR 2143, Jan. 13, 2006; 76 FR 20228, Apr. 12, 2011; 78 FR 59622, Sept. 27, 2013; 79 FR 56238, Sept. 19, 2014]

PART 392—PETITIONS FOR RULEMAKING

Sec.

AUTHORITY: 5 U.S.C. 553(e), 7 CFR 1.28.

SOURCE: 74 FR 16107, Apr. 9, 2009, unless otherwise noted.

§ 392.1 Scope and purpose.

This part contains provisions governing the submission of petitions for rulemaking to the Food Safety and Inspection Service (FSIS). The provisions in this part apply to all rulemaking petitions submitted to FSIS, except to the extent that other parts or sections of this chapter prescribe procedures for submitting a request to amend a particular regulation.

§ 392.2 Definition of petition.

For purposes of this part, a ''petition'' is a written request to issue, amend, or repeal a regulation administered by FSIS. A request to issue, amend, or repeal a document that interprets a regulation administered by FSIS may also be submitted by petition.

§ 392.3 Required information.

To be considered by FSIS, a petition must contain the following information:

(a) The name, address, telephone number, and e-mail address (if available) of the person who is submitting the petition;

(b) A full statement of the action requested by the petitioner, including the exact wording and citation of the existing regulation, if any, and the proposed regulation or amendment requested;

(c) A full statement of the factual and legal basis on which the petitioner relies for the action requested in the petition, including all relevant information and views on which the petitioner relies, as well as information known to the petitioner that is unfavorable to the petitioner's position. The statement should identify the problem that the requested action is intended to address and explain why the requested action is necessary to address the problem.

§ 392.4 Supporting documentation.

(a) Information referred to or relied on in support of a petition should be included in full and should not be incorporated by reference. A copy of any article or other source cited in a petition should be submitted with the petition.

(b) Sources of information that are appropriate to use in support of a petition include, but are not limited to:

(1) professional journal articles,

(2) research reports,

(3) official government statistics,

(4) official government reports,

(5) industry data, and

(6) scientific textbooks.

(c) If an original research report is used to support a petition, the information should be presented in a form that would be acceptable for publication in a peer reviewed scientific or technical journal.

(d) If quantitative data are used to support a petition, the presentation of the data should include a complete statistical analysis using conventional statistical methods.

§ 392.5 Filing procedures.

(a) Any interested person may file a petition with FSIS. For purposes of this part, an ''interested person'' is any individual, partnership, corporation, association, or public or private organization.

(b) To file a petition with FSIS, a person should submit the petition to the FSIS Docket Clerk, Department of Agriculture, Food Safety and Inspection Service, Room 2534 South Building, 1400 Independence Ave., SW., Washington, DC 20250–3700.

(c) Once a petition is submitted in accordance with this part, it will be filed by the FSIS Docket Clerk, stamped with the date of filing, and assigned a petition number. Once a petition has been filed, FSIS will notify the petitioner in writing and provide the petitioner with the number assigned to the petition and the Agency contact for the petition. The petition number should be referenced by the petitioner in all contacts with the Agency regarding the petition.

(d) If a petitioner elects to withdraw a petition submitted in accordance with this part, the petitioner should inform FSIS in writing. Once a petition has been withdrawn, the petitioner may re-submit the petition at any time.

§ 392.6 Public display.

(a) All rulemaking petitions filed with FSIS, along with any documentation submitted in support of a petition, will be available for public inspection in the FSIS docket room and will be posted on the FSIS Web site at *http://www.fsis.usda.gov/*.

(b) If FSIS cannot readily determine whether information submitted in support of a petition is privileged or confidential business information, FSIS will request that the petitioner submit a written statement that certifies that the petition does not contain confidential information that should not be put on public display. If the petitioner fails to submit the certification within a time specified by FSIS, the Agency will consider the information to be confidential.

(c) If FSIS determines that a petition, or any documentation submitted in support of a petition, contains information that is exempt from public disclosure under the Freedom of Information Act (5 U.S.C. 552 *et seq.*) or any other applicable laws or regulations, and that the information would provide the basis for granting the petition, FSIS will inform the petitioner in writing. FSIS will provide the petitioner an opportunity to withdraw the petition or supporting documentation, or modify the supporting documentation to permit public disclosure.

§ 392.7 Comments.

(a) Any interested person may submit written comments on a petition filed with FSIS.

(b) Comments on a petition should be submitted within 60 days of the posting date of the petition and should identify the number assigned to the petition to which the comments refer.

(c) FSIS will consider all timely comments on a petition that are submitted in accordance with this section as part of its review of the petition.

(d) All comments on a petition will become part of the petition file and will be available for public inspection in the FSIS docket room and posted on the FSIS Web site at *http://www.fsis.usda.gov/*.

(e) Any interested person who wishes to suggest an alternative action to the action requested by the petition should submit a separate petition that complies with these regulations and not submit the alternative as a comment on the petition.

(f) If FSIS determines that a comment received on a petition is in fact a request for an alternative action, the Agency will inform the commenter in

writing. The Agency will take no further action on the requested alternative action unless the commenter submits an appropriate petition for rulemaking.

§ 392.8 Expedited review.

(a) A petition will receive expedited review by FSIS if the requested action is intended to enhance the public health by removing or reducing foodborne pathogens or other potential food safety hazards that might be present in or on meat, poultry, or egg products.

(b) For a petition to be considered for expedited review, the petitioner must submit scientific information that demonstrates that the requested action will reduce or remove foodborne pathogens or other potential food safety hazards that are likely to be present in or on meat, poultry, or egg products, and how it will do so.

(c) If FSIS determines that a petition warrants expedited review, FSIS will review the petition ahead of other pending petitions.

§ 392.9 Availability of additional guidance.

Information related to the submission and processing of petitions for rulemaking may be found on the FSIS Web site at *http://www/fsis.usda.gov/*.

SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

PART 412—LABEL APPROVAL

Sec.
412.1 Label approval.
412.2 Approval of generic labels.

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 78 FR 66838, Nov. 7, 2013, unless otherwise noted.

§ 412.1 Label approval.

(a) No final label may be used on any product unless the label has been submitted for approval to the FSIS Labeling and Program Delivery Staff, accompanied by FSIS Form 7234–1, Application for Approval of Labels, Marking, and Devices, and approved by such staff, except for generically approved labels authorized for use in § 412.2. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, must maintain a copy of all labels used, in accordance with parts 320 and 381, subpart Q, of this chapter. Such records must be made available to any duly authorized representative of the Secretary upon request.

(b) All labels required to be submitted for approval as set forth in paragraph (a) of this section will be submitted to the FSIS Labeling and Program Delivery Staff. A parent company for a corporation may submit only one label application for a product produced in other establishments that are owned by the corporation.

(c) The Food Safety and Inspection Service requires the submission of labeling applications for the following:

(1) Sketch labels as defined in paragraph (d) of this section for products which are produced under a religious exemption;

(2) Sketch labels for products for foreign commerce whose labels deviate from FSIS regulations, with the exception of printing labels in foreign language or printing labels that bear a statement of the quantity of contents in accordance with the usage of the country to which exported as described in § 317.7 and part 381, subpart M of this chapter.

(3) Special statements and claims as defined in paragraph (e) of this section and presented in the context of a final label.

(4) Requests for the temporary use of final labels as prescribed in paragraph (f) of this section.

(d) A ''sketch'' label is the concept of a label. It may be a printer's proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location. The Food Safety and Inspection Service will accept sketches that are hand drawn or computer generated, or other reasonable facsimiles that clearly reflect and project the final version of the label.

(e) ''Special statements and claims'' are claims, logos, trademarks, and other symbols on labels that are not defined in the Federal meat and poultry products inspection regulations or the Food Standards and Labeling Policy Book, (except for ''natural'' and negative claims (e.g., ''gluten free'')), health claims, ingredient and processing method claims (e.g., high-pressure processing), structure-function claims, claims regarding the raising of animals, organic claims, and instructional or disclaimer statements concerning pathogens (e.g., ''for cooking only'' or ''not tested for *E. coli* O157:H7''). Examples of logos and symbols include graphic representations of hearts and geographic landmarks. Special statements and claims do not include allergen statements (e.g., ''contains soy'') applied in accordance with the Food Allergen Labeling and Consumer Protection Act.

(f)(1) Temporary approval for the use of a final label that may be deemed deficient in some particular may be granted by the FSIS Labeling and Program Delivery Staff. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

(i) The proposed label would not misrepresent the product;

(ii) The use of the label would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the FSIS Labeling and Program Delivery Staff provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

§412.2 Approval of generic labels.

(a)(1) An official establishment, or an establishment certified under a foreign inspection system in accordance with part 327, or part 381, subpart T of this chapter, is authorized to use generically approved labels, as defined in paragraph (b) of this section, and thus is free to use such labels without submitting them to the Food Safety and Inspection Service for approval, provided the label, in accordance with this section, displays all mandatory features in a prominent manner in compliance with part 317 or part 381, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service will select samples of generically approved labels from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 or part 381, subpart T, to determine compliance with label requirements. If the Agency finds that an establishment is using a false or misleading label, it will institute the proceedings prescribed in §500.8 of this chapter to revoke the approval for the label.

(b) Generically approved labels are labels that bear all applicable mandatory labeling features (i.e., product name, safe handling statement, ingredients statement, the name and place of business of the manufacturer, packer or distributor, net weight, legend, safe handling instructions, and nutrition labeling) in accordance with Federal regulations. Labels that bear claims and statements that are defined in FSIS's regulations or the Food Standards and Labeling Policy Book (except for natural and negative claims), such as a statement that characterizes a product's nutrient content, such as ''low fat,'' has geographical significance, such as ''German Brand,'' or makes a country of origin statement on the label of any meat or poultry product ''covered commodity'',[1] and that comply with those regulations are also deemed to be generically approved by the Agency without being submitted for evaluation and approval. Allergen statements (e.g., ''contains soy'') applied in accordance with the Food Allergen Labeling and Consumer Protection Act are also deemed generically approved.

PART 416—SANITATION

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 61 FR 38868, July 25, 1996, unless otherwise noted.

§416.1 General rules.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

[64 FR 56417, Oct. 20, 1999]

§416.2 Establishment grounds and facilities.

(a) *Grounds and pest control.* The grounds about an establishment must be maintained to prevent conditions

[1] See 9 CFR 317.8(b)(40) and 381.129(f).

that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

(b) *Construction.* (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

(c) *Light.* Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

(d) *Ventilation.* Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

(e) *Plumbing.* Plumbing systems must be installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the establishment;

(2) Properly convey sewage and liquid disposable waste from the establishment;

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases.

(f) *Sewage disposal.* Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) *Water supply and water, ice, and solution reuse.* (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) *Dressing rooms, lavatories, and toilets.* (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

[64 FR 56417, Oct. 20, 1999]

§ 416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

[64 FR 56417, Oct. 20, 1999]

§ 416.4 Sanitary operations.

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

[64 FR 56417, Oct. 20, 1999]

§ 416.5 Employee hygiene.

(a) *Cleanliness.* All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) *Clothing.* Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) *Disease control.* Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

[64 FR 56417, Oct. 20, 1999]

§ 416.6 Tagging insanitary equipment, utensils, rooms or compartments.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a ''U.S. Rejected'' tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a ''U.S. Rejected'' tag.

[64 FR 56417, Oct. 20, 1999]

§ 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§ 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

[61 FR 38868, July 25, 1996, as amended at 62 FR 26219, May 13, 1997]

§ 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§ 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 451–472, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 61 FR 38868, July 25, 1996, unless otherwise noted.

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE *Food Safety Hazard.*

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority onsite or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) *Hazard analysis.* (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;

(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) *The HACCP plan.* (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter—all species.

(ii) Raw product—ground.

(iii) Raw product—not ground.

(iv) Thermally processed—commercially sterile.

(v) Not heat treated—shelf stable.

(vi) Heat treated—shelf stable.

(vii) Fully cooked—not shelf stable.

(viii) Heat treated but not fully cooked—not shelf stable.

(ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 431 of this chapter.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with §417.4 of this part.

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under §417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

[61 FR 38868, July 25, 1996, as amended at 62 FR 61009, Nov. 14, 1997; 83 FR 25308, May 31, 2018]

§417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if

another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) *Initial validation.* Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) *Ongoing verification activities.* Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3)(i) *Reassessment of the HACCP plan.* Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

[61 FR 38868, July 25, 1996, as amended at 77 FR 26936, May 8, 2012]

§417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

(d) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) *Record retention.* (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by §417.3 of this part;

(d) HACCP records are not being maintained as required in §417.5 of this part; or

(e) Adulterated product is produced or shipped.

§417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with §417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with §417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this

section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

PART 418—RECALLS

Sec.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 77 FR 26936, May 8, 2012, unless otherwise noted.

§ 418.1 [Reserved]

§ 418.2 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

§ 418.4 Records.

All records, including records documenting procedures required by this part, must be available for official review and copying.

PART 424—PREPARATION AND PROCESSING OPERATIONS

Subpart A—General

Sec.

Subpart C—Food Ingredients and Sources of Radiation

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 451–472, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 64 FR 72175, Dec. 23, 1999, unless otherwise noted.

Subpart A—General

§ 424.1 Purpose and scope.

This part of the regulations prescribes rules for the preparation of meat and the processing of poultry products. The rules in this part further the purposes of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by, among other things, preventing the adulteration or misbranding of meat and poultry products at official establishments. 9 CFR Chapter III, Subchapter A, Parts 318 and 319, Subpart C

of this part, and 21 CFR Chapter I, Subchapter A or Subchapter B, specify rules for the use of certain food ingredients (e.g., food additives and color additives) and sources of radiation that may render meat or poultry products adulterated or misbranded.

Subpart C—Food Ingredients and Sources of Radiation

§ 424.21 Use of food ingredients and sources of radiation.

(a)(1) *General.* No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, part 318 or part 319 of this chapter, or by the Administrator in specific cases.

(2)(i) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment or imported from a foreign country listed in §381.196(b), and have been inspected and passed in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed for use as human food in a manner approved by the Administrator in specific cases and detached ova may be used in the processing of poultry products if the processor demonstrates that such ova comply with the requirements of the Federal Food, Drug, and Cosmetic Act.

(ii) Liquid, frozen, and dried egg products used in the processing of any poultry product shall have been prepared under inspection and be so marked in accordance with the Egg Products Inspection Act.

(3) Carcasses, parts thereof, and products of cattle, sheep, swine, goats, or equines may be used in the processing of poultry products only if they were prepared in the United States in an official meat packing establishment or imported from a foreign country listed in §327.2(b), were inspected and passed in accordance with the Federal Meat Inspection Act and the regulations under such Act (subchapter A of this chapter), and are so marked.

(b)(1) *Food ingredients and sources of radiation.* Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry products in 21 CFR chapter I, subchapter A or subchapter B, shall be listed for such use under this chapter, subject to declaration requirements in parts 316 and 317, or subparts M and N, of part 381 of this chapter, unless precluded from such use or further restricted in parts 318 or 319, or subparts O and P, of part 381 of this chapter, or unless such use otherwise results in the adulteration or misbranding of meat or poultry products. Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry products in 21 CFR Chapter I, subchapter A or subchapter B, may be listed or approved for such use under this chapter by the Administrator in §424.21, subject to declaration requirements in parts 316 and 317, or subparts M and N, of part 381 of this chapter.

(2) No food ingredients or sources of radiation may be used in the preparation of any meat or poultry product, for any purpose, unless the use is listed or approved in 21 CFR chapter I as a direct food additive (21 CFR part 172), a secondary direct food additive (21 CFR part 173), indirect food additive (21 CFR parts 174–178), radiation source (21 CFR part 179), an interim-listed direct food additive (21 CFR part 180), a prior-sanctioned substance (21 CFR part 181), a Generally Recognized As Safe (GRAS) substance (21 CFR parts 182 or 184), or by a regulation in this chapter. Part 319 of this chapter also specifies other food ingredients that are acceptable in preparing specified products.

(3) No food ingredient, the intended use of which is to impart color in any meat or poultry product, shall be used unless such use is approved in 21 CFR chapter I as a color additive (21 CFR Parts 73, 74, 81, and 82) or in a regulation in this chapter.

(4) Petitions to amend 21 CFR chapter I to provide for uses of food additives, or other substances or sources of radiation necessary in the preparation of meat or poultry products, or food ingredients used to impart color to product, should be sent to the Food and

Drug Administration, in accordance with the provisions of 21 CFR parts 71 or 171, as appropriate.

(5) Inquiries concerning the regulatory status under the Federal Food, Drug, and Cosmetic Act of any articles intended for use as components of, or in contact with, meat or poultry products, may be addressed to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204, or the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development and Evaluation, Washington, DC 20250–3700.

(6) Inquiries concerning the use in specific meat or poultry products of substances that are not affirmed by the Food and Drug Administration as Generally Recognized as Safe (GRAS) or otherwise listed in 21 CFR part 182 or part 184, or of food or color additives listed in 21 CFR regulations for general use in foods or for use in meat, or poultry products, generally, including mixtures of such substances or additives, should be addressed to the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development and Evaluation, Washington, DC 20250–3700.

(c) The food ingredients specified in the following chart are approved for use in the preparation of meat products, provided they are used for the purposes indicated, within the limit of the amounts stated, and under other conditions specified in this part and Part 317 of this chapter. Part 319 of this chapter specifies other food ingredients that are acceptable in preparing specified meat products. This chart also contains food ingredients that are acceptable for use in poultry products, provided they are used for the purpose indicated, within the limits of the amounts stated and under other conditions specified in this part. No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, or by the Administrator in specific cases.

Class of substance	Substance	Purpose	Products	Amount
Acidifiers	Acetic acid	To adjust acidity	Various meat and poultry products[2].	Sufficient for purpose.[3]
	Citric acid	...do	...do	Do.
	Glucono delta-lactone.	...do	...do	Do.
	Lactic acid	...do	...do	Do.
	Phosphoric acid	...do	...do	Do.
	Tartaric acid	...do	...do	Do.
Anti-coagulants	Citric acid	To prevent clotting	Fresh blood of livestock	0.2 percent with or without water. When water is used to make a solution of citric acid added to the blood of livestock, not more than 2 parts of water to 1 part of citric acid shall be used.
	Sodium citrate	...do	...do	Not to exceed 0.5 percent based on the ingoing weight of the product. When water is used to make a solution of sodium citrate added to livestock blood, not more than 2 parts of water to 1 part of sodium citrate shall be used.
Antifoaming agent	Methyl polysilicone	To retard foaming	Soups (meat and poultry)	10 ppm.
		...do	Rendered fats (meat and poultry).	Do.
		...do	Curing pickle (meat and poultry).	50 ppm.
Antimicrobial Agents	Potassium lactate	To inhibit microbial growth.	Various meat and poultry products, except infant formulas and infant food.	4.8% by weight of total formulation.
	Sodium diacetate	...do	...do	0.25% by weight of total formulation.
	Sodium lactate	...do	...do	4.8% by weight of total formulation.

Class of substance	Substance	Purpose	Products	Amount
	Trisodium phosphate.	To reduce microbial levels.	Raw, chilled poultry carcasses.	8 to 12 percent; solution to be maintained at 45 °F. to 55 °F. and applied by spraying or dipping carcasses for up to 15 seconds when used in accordance with 21 CFR 182.1778.
Antioxidants and oxygen interceptors.	Ascorbyl palmitate ..	To retard rancidity ..	Margarine or oleomargarine	0.02 percent (by wt. of finished product) individually or in combination with other antioxidants approved for use in margarine.
	Ascorbyl stearate.			
	BHA (butylated hydroxyanisole).			
.....	.....do	Dry sausage	0.003 based on total weight	0.006 percent in combination with other anti-oxidants for use in meat.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.
	.....do	Margarine or oleomargarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine..	
	.....do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content..	
	BHT (butylated hydroxytoluene).	.....do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other anti-oxidants for use in meat.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.

Class of substance	Substance	Purpose	Products	Amount
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.
	.....do	Margarine or oleomargarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine..	
	.....do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content..	
	Dodecyl gallate	.....do	Margarine or oleomargarine	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine.
	Glycine	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent 0.02 percent in combination with other anti-oxidants for use in meat.
	Octyl gallate	.....do	Margarine or oleomargarine	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine.
	Propyl gallate	.....do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other anti-oxidants for use in meat.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.

Class of substance	Substance	Purpose	Products	Amount
	.....do	Margarine or oleomargarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine..	
	.....do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content)..	
	Resin guaiac	.....do	Rendered animal fat or a combination of such fat and vegetable fat 0.01 percent.	0.02 percent in combination with other antioxidants for use in meat.
	TBHQ (tertiary butylhydroquinone).	.....do	Dry sausage 0.003 percent based on weight.	0.006 percent in combination only with BHA and/or BHT.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination only with BHA or BHT.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination only with BHA and/or BHT, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination only with BHA and/or BHT.
		.....do	Margarine or oleo-margarine.	0.02 percent alone or in combination only with BHA and/or BHT, based on oil or fat content.
		.....do	Various poultry products	0.01 percent based on fat content (0.02 percent in combination only with BHA and/or BHT, based on fat content).
	Tocopherols	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.03 percent. A 30 percent concentration of tocopherols in vegetable oils shall be used when added as an antioxidant to products designated as ''lard'' or ''rendered pork fat.''
		.....do	Dry sausage, semidry sausage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausages, pregrilled beef patties, and restructured meats.	Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants.

Class of substance	Substance	Purpose	Products	Amount
		.....do	Various poultry products	0.03 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content).
Artificial Sweeteners	Saccharin	To sweeten product	Bacon	0.01 percent.
Binders and Extenders.	Agar-agar	To stabilize and thicken.	Thermally processed canned and jellied meat food products.	0.25 percent of finished product.
	Algin	To extend and stabilize product.	Breading mix; sauces (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
	A mixture of sodium alginate, calcium carbonate and calcium lactate/ lactic acid (or glucono delta lactone).	To bind meat pieces	Restructured meat food products.	Sodium alginate not to exceed 1.0 percent; calcium carbonate not to exceed 0.2 percent; and lactic acid/calcium lactate (or glucono delta-lactone) not to exceed 0.3 percent of product formulation. Added mixture may not exceed 1.5 percent of product at formulation. Mixture ingredients must be added dry.
	A mixture of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.	To bind poultry pieces.	Ground and formed raw or cooked poultry pieces.	Sodium alginate not more than 0.8 percent, calcium carbonate not more than 0.15 percent; lactic acid and calcium lactate, in combination, not more than 0.6 percent of product formulation. Added mixture may not exceed 1.55 percent of product at formulation. The mixture must be added in dry form.
	Bread	To bind and extend product.	Bockwurst	3.5 percent individually or collectively with other binders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
		.....do	Spaghetti with meat balls and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders for use in meat.
	Carboxymethyl cellulose (cellulose gum).	To extend and stabilize product.	Baked pies (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
	Carrageenan	To extend and stabilize product.	Breading mix; sauces (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
		To prevent purging of brine solution.	Cured pork products as provided in 9 CFR 319.104(d).	Not to exceed 1.5 percent of product formulation; permitted in combination only with soy protein concentrate, combination not to exceed 1.5 percent of product formulation; in accordance with 21 CFR 172.620, 172.623, and 172.626.

Class of substance	Substance	Purpose	Products	Amount
	Carrageenan, Locust bean gum, and Xanthan gum blend.	.....do	.....do	In combination, not to exceed 0.5 percent of formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, 172.626, 184.1343, and 172.695.
	Cereal	To bind and extend product.	Sausages as provided in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
	Dried milk	.....do	Sausages as provided for in 9 CFR Part 319.	3.5 percent individually or collectively with other binders for use in meat
	Dried skim milk, calcium reduced.	.....do	Sausages as provided in 9 CFR 9 CFR Part 319.	Do.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
	Enzyme (rennet) treated with calcium reduced dried skim milk and calcium lactate.	.....do	Sausages as provided for in 9 CFR Part 319.	3.5 percent total finished product (calcium lactate required at rate of 10 percent of binder.)
		.....do	Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 10 percent of binder).
	Enzyme (rennet) treated with sodium caseinate and calcium lactate.	.....do	Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 25 percent of binder).
	Food starch modified.	To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation in ''Ham Water Added'' and ''Ham with Natural Juices'' products; not to exceed 3.5 percent of product formulation in ''Ham and Water Product—X percent of Weight is Added Ingredients'' products; permitted in combination only with soy protein concentrate, with combination of modified food starch at 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in accordance with 21 CFR 172.892.
	Gelatin	To bind and extend product.	Various poultry products	Sufficient for purpose in accordance with 21 CFR 172.5.
	Gums, vegetable	.....do	Egg roll (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
	Isolated soy protein	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	2 percent.

Class of substance	Substance	Purpose	Products	Amount
		.....do	Imitation sausages; nonspecific loaves; soups; stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat.
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation, not permitted in combination with other binders approved for use in cured pork products.
	Methyl cellulose	To extend and stabilize product (also carrier).	Meat and vegetable patties; various poultry products.	0.15 percent.
	Sodium caseinate ...	To bind and extend product.	Imitation sausages, nonspecific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5.
		.....do	Sausages as provided for in 9 CFR Part 319.	2 percent in accordance with 21 CFR 182.1748.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat in accordance with 21 CFR 182.1748.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat in accordance with 21 CFR 182.1748.
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products, in accordance with 21 CFR 182.1748.
		To bind and extend product.	Various poultry products	3 percent in cooked product, 2 percent in raw product, in accordance with 21 CFR 172.5 and 182.1748.
	Soy flour	.....do	Sausages as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat.
	Soy protein concentrate.	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat.

Class of substance	Substance	Purpose	Products	Amount
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 3.5 percent of product formulation; permitted in combination only with modified food starch, with combination of modified food starch at 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in combination only with carrageenan, combination not to exceed 1.5 percent of product formulation.
	Starchy vegetable flour.	To bind and extend product.	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
	Tapioca dextrin	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277.
		.....do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1277.
	Vegetable starch	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
	Wheat gluten	To bind and extend product.	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1322.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat, in accordance with 21 CFR 184.1322.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1322.
		.....do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1322.

Class of substance	Substance	Purpose	Products	Amount
	Whey, Dry or dried	To bind or thicken ..	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Imitation sausages, nonspecific loaves, soups, stews (meat only).	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1322.
	Whey, Reduced lactose.	To bind or thicken ..	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Imitation sausages, nonspecific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat.
	Whey, Reduced minerals.	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Imitation sausages, nonspecific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat.
	Whey protein concentrate.	.....do	Sausage as provided in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c.
		.....do	Imitation sausages, nonspecific loaves, soups, stews.	Sufficient for purpose in accordance with 21 CFR 184.1979c.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c
		To bind meat pieces	Restructured meat food products, whole muscle meat cuts.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c.
	Xanthan gum	To maintain: uniform viscosity; suspension of particulate matter, emulsion stability; freeze-thaw stability.	Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes.	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Various poultry products, except uncooked products or sausages or other products with a moisture limitation established by Subpart P of Part 381.	Sufficient for purpose

Class of substance	Substance	Purpose	Products	Amount
Bleaching Agent	Hydrogen peroxide	To remove color	Tripe (substance must be removed from product by rinsing with clear water).	Sufficient for purpose.
Catalysts (substances must be eliminated during process).	Nickel	To accelerate chemical reaction.	Rendered animal fats or a combination of such fats and vegetable fats.	Do.
	Sodium amide	Rearrangement of fatty acid radicals.	.....do	Do.
	Sodium methoxide ..	.....do	.....do.	
Chilling Media	Salt (NaCl)	To aid in chilling	Raw poultry products	700 lbs. to 10,000 gallons of water.
Coloring Agents (artificial).	Coal tar dyes (FD&C certified).	To color products ...	Various poultry products	Sufficient for purpose.
	Color additives listed in 21 CFR Part 74, Subpart A of Part 82, Subpart B (operator must furnish evidence to inspector in charge that color additive has been certified for use in connection with foods by the Food and Drug Administration).	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product (meat only).	Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt and sugar).
	Titanium oxide	To whiten	Canned ham salad spread and creamed-type canned meat products. Poultry salads and poultry spreads.	0.5 percent.
Coloring Agents (natural).	Alkanet, annatto, carotene, cochineal, green chlorophyll, saffron and tumeric.	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product (meat only).	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar).
	Annatto, carotene ...	To color products ...	Various poultry products	Sufficient for purpose.
Curing accelerators (must be used only in combination with curing agents).	Ascorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Citric acid or sodium citrate.	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product, cured comminuted poultry or poultry products.	May be used in cured meat products or in 10 percent solution used to spray surfaces of cured meat cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used. May be used in cured poultry products to replace 50 percent of the ascorbic acid or sodium ascorbate that is used.

Class of substance	Substance	Purpose	Products	Amount
	Erythorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Fumaric acid	.....do	Cured, comminuted meat, poultry or meat and poultry products.	0.065 percent (or 1 oz to 100 lb) of the weight of the meat, poultry or the meat or poultry byproducts before processing.
	Glucono delta lactone.	.....do	Cured, comminuted meat or meat food product.	8 oz to each 100 lb of meat or meat byproduct.
		.....do	Genoa salami	16 oz to 100 lb of meat (1.0 percent).
	Sodium acid pyrophosphate.	.....do	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst and similar products.	Not to exceed alone or in combination with other curing accelerators for use in meat the following: 8 oz in 100 lb of meat, or meat and meat byproducts, content of the formula; nor 0.5 percent in the finished product.
	Sodium ascorbate ..	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product, cured comminuted poultry or poultry products.	87.5 oz to 100 gal pickle at 10 percent pump level; ⅞ oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Sodium erythorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food products, cured comminuted poultry or poultry products.	87.5 oz to 100 gal pickle at 10 percent pump level; ⅞ oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
Curing Agents	Sodium or potassium nitrate.	Source of nitrite	Cured meat products other than bacon. Nitrates may not be used in baby, junior, and toddler foods. Cured, comminuted poultry or poultry products.	7 lb to 100 gal pickle; 3½ oz to 100 lb meat or poultry product (dry cure); 2¾ oz to 100 lb chopped meat or poultry.

Class of substance	Substance	Purpose	Products	Amount
	Sodium or potassium nitrite (supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly).	To fix color	Cured meat and poultry products. Nitrites may not be used in baby, junior, or toddler foods.	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb meat or poultry product (dry cure); ¼ oz to 100 lb chopped meat, meat byproduct or poultry product. The use of nitrites, nitrates or combination shall not result in more than 200 ppm of nitrite, calculated as sodium nitrite in finished product, except that nitrites may be used in bacon only in accordance with paragraph (b) of this section.
Denuding Agents (may be used in combination. Must be removed from tripe by rinsing with potable water.).	Lime (calcium oxide, calcium hydroxide).	To denude mucous membranes.	Tripe	Sufficient for purpose.
	Sodium carbonate	...do	...do	Do.
	Sodium citrate	...do	...do	Do.
	Sodium gluconate	...do	...do	Do.
	Sodium hydroxide	...do	...do	Do.
	Sodium persulfate	...do	...do	Do.
	Sodium silicates (ortho, meta, and sesqui).	...do	...do	Do.
	Trisodium phosphate.	...do	...do	Do.
Emulsifying Agents	Actylated monoglycerides.	To emulsify product	Shortening and various poultry products.	Sufficient for purpose.
	Diacetyl tartaric acid esters of mono- and diglycerides.	...do	...do	Do.
	Glycerol-lacto stearate, oleate, or palmitate.	...do	...do	Do.
	Lecithin	To emulsify product (also as an antioxidant).	Oleomargarine, shortening, various meat and poultry products.	0.5 percent in oleomargarine, use in other products—sufficient amount for emulsification.
	Mono and diglycerides (glycerol palmitate, etc.).	To emulsify product	Rendered animal fat or a combination of such fat with vegetable fat; oleomargarine.	Sufficient for purpose in lard and shortening; 0.5 percent in oleomargarine.
		...do	Various poultry products	Sufficient for purpose.
	Mono and diglycerides of fatty acids esterified with any of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts; the sodium sulfoacetate derivatives of these mono and diglycerides.	...do	Margarine or oleomargarine	0.5 percent.

Class of substance	Substance	Purpose	Products	Amount
	Polyglycerol esters of fatty acids (polyglycerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of § 172.854(a) of the Food Additive Regulations).	.....do	Rendered animal fat or a combination of such fat with vegetable fat when use is not precluded by standards of identity of composition; oleomargarine.	Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5 percent for oleomargarine.
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate).	.....do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods (meat only). Rendered poultry fat or a combination of such fat with vegetable fat.	1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 percent.
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).	.....do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods (meat only). Various poultry products.	1 percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 percent.
	1,2-propylene glycol esters of fatty acids.	.....do	Margarine or oleomargarine	2.0 percent.
	Propylene glycol mono and diesters of fats and fatty acids.	.....do	Rendered animal or poultry fat or a combination of such fat with vegetable fat.	Sufficient for purpose.
	Stearyl-2-lactylic acid.	.....do	Shortening to be used for cake icings and fillings (meat only).	3.0 percent.
	Stearyl monoglyceridyl citrate.	.....do	Shortening	Sufficient for purpose
Film Forming Agents	A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethylcellulose, and corn syrup solids.	To reduce cooler shrinkage and help protect surface.	Freshly dressed meat carcasses. Such carcasses must bear a statement ''Protected with a film of water, corn syrup solids, sodium alginate, calcium chloride and sodium carboxymethyl-cellulose.''.	Formulation may not exceed 1.5 percent of hot carcass weight when applied. Chilled weight may not exceed hot weight.
Flavoring Agents; Protectors and Developers.	Artificial smoke flavoring.	To flavor product	Various (meat and poultry) [2]	Sufficient for purpose.
	Autolyzed yeast extract.	.....do	.....do	Do.
	Benzoic acid (sodium, potassium and calcium salts).	To retard flavor reversion.	Margarine or oleomargarine	0.1 percent individually, or if used in combination with other flavoring agents for use in meat or with sorbic acid and its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Calcium lactate	To protect flavor	Cooked semi-dry and dry products including sausage, imitation sausage, and nonspecific meat food sticks.	0.6 percent in product formulation.
	Citric acid	.....do	Various poultry products	Sufficient for purpose.
		Flavoring	Chili con carne	Do.

Class of substance	Substance	Purpose	Products	Amount
	Corn syrup solids; corn syrup; glucose syrup.	To flavor product	Various poultry products, sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham.	Do.
	Dextrose	.....do	Sausage, ham and cured products.	Do.
	Diacetyl	.....do	Oleomargarine	Do.
	Disodium guanylate	.....do	Various meat and poultry products.[2]	
	Disodium inosinate	.....do	.....do	Do.
	Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of *Pediococcus cerevisiae*.	To develop flavor	Dry sausage, pork roll, thuringer, lebanon bologna, cervelat, and salami.	0.5 percent.
	Harmless lactic acid producing bacteria.	To prevent the growth of *Clostridium botulinum*.	Bacon	Sufficient for purpose.
	Hydrolyzed plant protein.	To flavor product	Various meat and poultry products.[2]	Do.
	Isopropyl citrate	To protect flavor	Oleomargarine	0.02 percent.
	Malt syrup	To flavor product	Cured meat products	2.5 percent.
		.....do	Various poultry products	Sufficient for purpose.
	Milk protein hydrolysate.	.....do	Various meat and poultry products.[2]	Do.
	Monoammonium glutamate.	.....do	.....do	Do.
	Monosodium glutamate.	.....do	.....do	Do.
	Potassium lactate ...	.....do	Various meat and meat food products, poultry and poultry food products, except infant formula and infant food.[2]	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Smoke flavoring	To flavor product	Various meat and poultry products.	Sufficient for purpose.
	Sodium acetate	To flavor products ..	Various meat and poultry products.	Not to exceed 0.25% of formulate in accordance with 21 CFR 184.1721.
	Sodium diacetate	.....do	.....do	Not to exceed 0.25% of formulate in accordance with 21 CFR 184.1754.
	Sodium lactate	.....do	Various meat and meat food products, poultry and poultry food products, except infant formula and infant food.[2]	Not to exceed 2 percent of formulation in accordance with 21 CFR 184.1768.
	Sodium sulfoacetate derivative of mono and diglycerids.	.....do	Various meat and poultry products.[2]	0.5 percent.
	Sodium tripolyphosphate.	To help protect flavor.	"Fresh Beef,"[2] "Beef for further cooking, "Cooked Beef," Beef Patties, Meat Loaves, Meat Toppings, and similar products derived from pork, lamb, veal, mutton, and goat meat which are cooked or frozen after processing.	0.5 percent of total product.
	Sodium tripolyphosphate and sodium mixtures, metaphosphate, insoluble; and sodium polyphosphates, glassy.	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sorbitol	To flavor, to facilitate the removal of casings from product, and to reduce caramelization and charring.	Cooked sausage labeled frankfurter, frank, furter, wiener, and knockwurst; cured pork and pork products, as provided for in 9 CFR Part 319.	Not to exceed 2 percent of the weight of the formula excluding the formula weight of water or ice, when used in accordance with 21 CFR 184.1835.
	Starter distillate	To help protect flavor.	Oleomargarine	Sufficient for purpose.
	Stearyl citrate	...do	...do	0.15 percent.
	Sugars (sucrose and dextrose).	To flavor product	Various meat and poultry products.	Sufficient for purpose.
Gases	Carbon dioxide liquid.	Contact freezing	Various poultry products	Do.
	Carbon dioxide solid (dry ice).	To cool product	Chopping of meat, packing of product.	Sufficient for purpose.
		To cool product or facilitate chopping or packaging.	Various poultry products	Do.
	Nitrogen	To exclude oxygen from sealed containers.	Various meat and poultry products.	Do.
	Nitrogen, liquid	Contact freezant	...do	Do.
Hog Scald Agents (must be removed by subsequent cleaning operations).	Caustic soda	To remove hair	Hog carcasses	Sufficient for purpose.
	Dicotyl sodium sulfosuccinate.	...do	...do	Do.
	Dimethylpolysiloxane.	...do	...do	Do.
	Disodium-calcium ethylenediaminetetra-acetate.	...do	...do	Do.
	Disodium phosphate	...do	...do	Do.
	Ethylenediaminetetra-acetic acid (sodium salts).	...do	...do	Do.
	Lime (calcium oxide, calcium hydroxide).	...do	...do	Do.
	Potassium hydroxide.			Do.
	Propylene glycol	...do	...do	Do.
	Soap (prepared by the reaction of calcium, potassium, or sodium with rosin or fatty acids of natural fats and oils).	...do	...do	Do.
	Sodium acid pyrophosphate.	...do	...do	Do.
	Sodium carbonate	...do	...do	Do.
	Sodium dodecylbenzene sulfonate.	...do	...do	Do.
	Sodium gluconate	...do	...do	Do.
	Sodium hexametaphosphate.	...do	...do	Do.
	Sodium lauryl sulfate.	...do	...do	Do.
	Sodium mono and dimethylnaphthalene sulfonate (molecular weight 245–260).	...do	...do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sodium n-alkylbenzene sulfonate (alkyl group predominantly C12 and C13 and not less than 95 percent C10 and C16).	.....do	.....do	Do.
	Sodium pyrophosphate.	.....do	.....do	Do.
	Sodium silicates (ortho, meta, and sesqui).	.....do	.....do	Do.
	Sodium sulfate	.....do	.....do	Do.
	Sodium tripolyphosphate.	.....do	.....do	Do.
	Sucrose	.....do	.....do	Do.
	Triethanolamine dodecylbenzene sulfonate.	.....do	.....do	Do.
	Trisodium phosphate.	.....do	.....do	Do.
Miscellaneous	Adipic acid	To acidify	Margarine or oleomargarine	Sufficient for purpose.
	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination.	To delay discoloration.	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751).
	Calcium disodium, EDTA (calcium disodium ethylenediaminetetraacetate.	To preserve product and to protect flavor.	Margarine or oleomargarine	75 ppm by weight of the finished oleomargarine or margarine.
	Calcium propionate	To retard mold growth.	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
		.....do	Fresh pie dough (poultry only).	0.3 percent of calcium propionate or sodium propionate alone, or in combination, based on weight of flour used.
	Citric acid	To preserve cured color during storage.	Cured pork cuts	Not to exceed 30 percent in water solution used to spray surfaces of cured cuts, prior to packaging, in accordance with 21 CFR 184.1033. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to product).
	Citric acid (sodium and potassium salts).	To acidify	Margarine and oleomargarine.	Sufficient for purpose.
	d- and dl-alpha-tocopherol.	To inhibit nitrosamine formation.	Pump-cured bacon	500 ppm; by injection or surface application.

Class of substance	Substance	Purpose	Products	Amount
	Dipotassium phosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.
	Disodium phosphate	.....do	.....do	Do.
	Glycerine	Humectant	Shelf stable meat snacks ...	Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320.
	Hydrochloric acid	To acidify	Margarine or oleomargarine	Sufficient for purpose.
	Lactic acid (sodium and potassium salts).	.....do	.....do	Do.
	L-Tartaric acid (sodium and sodium potassium salts).	.....do	.....do	Do.
	Monopotassium phosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Monosodium phosphate.	.....do	.....do	Do.
	Phosphoric acid	To acidify	Margarine or oleomargarine	Sufficient for purpose.
	Potassium bicarbonate.	To alkalize	Margarine or oleomargarine	Sufficient for purpose.
	Potassium carbonate.	.....do	.....do	Do.
	Potassium pyrophosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.
	Potassium sorbate ..	To retard mold growth.	Dry sausage	10 percent in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing.
	Potassium tripolyphosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.
	Propyl paraben (propyl p-hydroxybenzoate).	To retard mold growth.	Dry sausage	3.5 percent in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing.
	Silicon dioxide	Processing aid/dispersant.	Tocopherol containing bacon curing mixes.	At level not to exceed 4.0 percent in the dry mix.

Class of substance	Substance	Purpose	Products	Amount
	Sodium acid pyrophosphate.	To decrease the amount of cooked out juices.	Meat food products except where other prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Sodium bicarbonate	To neutralize excess acidity, cleaning vegetables.	Rendered fats, soups, curing pickle (meat and poultry).	Sufficient for purpose.
		To alkalize	Margarine or oleomargarine	Do.
	Sodium carbonate ..	.....do	.....do	Do.
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, processed whole muscle meat and poultry food products, e.g., ham, chicken breasts.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
	Sodium hydroxide ...	To alkalize	Margarine or oleomargarine	Sufficient for purpose.
		To decrease the amount of cooked out juices.	Poultry food products containing phosphates.	May be used only in combination with phosphate in a ratio not to exceed one part sodium hydroxide to four parts phosphate.
		.....do	Meat food products containing phosphates.	May be used only in combination with phosphates in a ratio not to exceed one part sodium hydroxide to four parts phosphate; the combination shall not exceed 5 percent in pickle at 10 percent pump level; 0.5 percent in product.
	Sodium metaphosphate, insoluble.	.....do	Meat food products except where other prohibited by the meat inspection regulations, and poultry food products except where otherwise prohibited by the poultry products inspection regulations.	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Sodium polyphosphate, glassy.	.....do	.....do	Do.
	Sodium proprionate	To retard mold growth.	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
		.....do	Fresh pie dough (poultry only).	0.3 percent of calcium proprionate or sodium proprionate alone, or in combination, based on weight of flour used.
	Sodium pryophosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Sodium tripolyphosphate.	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sorbic acid (sodium, potassium, and calcium salts).	To preserve product and to retard mold growth.	Margarine or oleomargarine	0.1 percent individually, or if used in combination or with benzoic acid or its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Tricalcium phosphate.	To preserve product color during dehydration process.	Mechanically deboned chicken to be dehydrated.	Not to exceed 2 percent of the weight of the mechanically deboned chicken prior to dehydration, in accordance with 21 CFR 182.1217.
Poultry scald agents (must be removed by subsequent cleaning operations).	Alpha-hydro-omega-hydroxy-poly (oxyethylene) poly (oxypropylene) (minimum 15 moles) poly (oxyethylene) block copolymer (poloxamer).	To remove feathers	Poultry carcasses	Not to exceed 0.05 percent by weight in scald water.
	Dimethylpolysiloxane.	.....do	.....do	Sufficient for purpose.
	Dioctyl sodium sulfosuccinate.	.....do	.....do	Do.
	Dipotassium phosphate.	.....do	.....do	Do.
	Ethylenediaminetetra-acetic acid (sodium salts).	.....do	.....do	Do.
	Lime (calcium oxide, calcium hydroxide).	.....do	.....do	Do.
	Polyoxyethylene (20) sorbitan monooleate.	.....do	.....do	Not to exceed 0.0175 percent in scald water.
	Potassium hydroxide.	.....do	.....do	Sufficient for purpose.
	Propylene glycol	.....do	.....do	Do.
	Sodium acid phosphate.	.....do	.....do	Do.
	Sodium acid pyrophosphate.	.....do	.....do	Do.
	Sodium bicarbonate	.....do	.....do	Do.
	Sodium carbonate	.....do	.....do	Do.
	Sodium dodecylbenzenesulfonate.	.....do	.....do	Do.
	Sodium-2-ethylhexyl sulfate.	.....do	.....do	Do.
	Sodium hexametaphosphate.	.....do	.....do	Do.
	Sodium hydroxide	.....do	.....do	Do.
	Sodium lauryl sulfate.	.....do	.....do	Do.
	Sodium phosphate (mono-, di-, tribasic).	.....do	.....do	Do.
	Sodium pyrophosphate.	.....do	.....do	Do.
	Sodium sesquicarbonate.	.....do	.....do	Do.
	Sodium sulfate	.....do	.....do	Do.
	Sodium tripolyphosphate.	.....do	.....do	Do.
	Tetrasodium pyrophosphate.	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
Proteolytic Enzymes	Aspergillus flavus oryzae group.	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus oryzae ..	.....do	.....do	Do.
	Bromelin	.....do	.....do	Do.
	Ficin	.....do	.....do	Do.
	Papain	.....do	.....do	Do.
Refining Agents (must be eliminated during process of manufacturing).	Acetic acid	To separate fatty acids and glycerol.	Rendered fats (meat only) ..	Sufficient for purpose.
	Bicarbonate of soda	.....do	.....do	Do.
	Carbon (purified charcoal).	To aid in refining of animal fats.	.....do	Do.
	Caustic soda (sodium hydroxide).	To refine fats	.....do	Do.
	Diatomaceous earth; Fuller's earth.	.....do	.....do	Do.
	Sodium carbonate ..	.....do	.....do	Do.
	Tannic acid	.....do	.....do	Do.
Rendering agents	Tricalcium phosphate.	To aid rendering	Animal fats	Do.
	Trisodium phosphate.	.....do	.....do	Do.
Synergists (used in combination with antioxidants).	Citric acid	To increase effectiveness of antioxidants.	Any meat product permitted to contain antioxidants as provided for in this part.	Not to exceed 0.01 percent based on fat content.
		.....do	Poultry fats	0.01 percent alone or in combination with antioxidants in poultry fats.
	Malic acid	.....do	Lard and shortening	0.01 percent based on total weight in combination with antioxidants for use in meat products only.
		.....do	Poultry fats	0.01 percent alone or in combination with antioxidants in poultry fats.
	Monoglyceride citrate.	.....do	Lard, shortening, fresh pork sausage, dried meats and poultry fats.	0.02 percent.
	Monoisopropyl citrate.	.....do	Lard, shortening, oleomargarine, fresh pork sausage, dried meats.	Do.
		.....do	Poultry fats	0.01 percent poultry fats.
	Phosphoric acid	.....do	Lard, shortening, and poultry fats.	0.01 percent.
Tenderizing agents ..	Aspergillus flavus oryzae group.	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus oryzae ..	.....do	.....do	Not more than 3 percent of a 0.8 molar solution.
	Bromelin	.....do	.....do	Do.
	Calcium chloride	.....do	.....do	Do.
	Magnesium chloride	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Papain	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Potassium chloride	do	do	Not more than 3 percent of a 2.0 molar solution.
	Potassium, magnesium or calcium chloride.	do	do	A solution of approved inorganic chlorides injected into or applied to raw meats or poultry cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.

[1] [Reserved]
[2] Information as to the specific products for which use of this additive is approved may be obtained upon inquiry addressed to the Labeling and Additives Policy Division, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.
[3] Provided that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under part 412 of this chapter.
[4] Special labeling requirements are prescribed in 381.120 for raw poultry chilled in a medium with more than 70 lbs. of salt to 10,000 gals. of water.

[64 FR 72175, Dec. 23, 1999, as amended at 65 FR 3123, Jan. 20, 2000; 65 FR 34391, May 30, 2000; 78 FR 66839, Nov. 7, 2013; 83 FR 25308, May 31, 2018]

§ 424.22 Certain other permitted uses.

(a) Under appropriate declaration as required in parts 316 and 317 of this chapter, the following substances may be added to meat:

(1) *General.* Common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other food and color additives specified in the chart in paragraph (c) of this section may be added to meat under conditions, if any, specified in this part or in part 317 of this chapter.

(2) *Artificial flavorings.* Other harmless artificial flavorings may be added to meat, with the approval of the Administrator in specific cases.

(3) *Coloring matter and dyes.* Coloring matter and dyes, other than those specified in a regulation permitting that use in this chapter or in 21 CFR Chapter I, Subchapter A and Subchapter B, may be applied to meat mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.

(b) *Use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon*—(1) *Pumped bacon.* With respect to bacon injected with curing ingredients and massaged bacon, sodium nitrite shall be used at 120 parts per million (ppm) ingoing or an equivalent amount of potassium nitrite shall be used (148 ppm ingoing); and 550 ppm of sodium ascorbate or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 ppm of sodium ascorbate or sodium erythorbate.

(i) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the Thermal Energy Analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be

collected and analyzed by gas chromatography. Presumptive positive results must be confirmed by mass spectrometry before being considered positive. If during the interval required for the Department to analyze the confirmatory samples by gas chromatography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitrosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA shall proceed in its confirmation analysis on the original samples taken for confirmation. If any one of the original samples collected by USDA for confirmation is found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to ensure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Bacon subsequently produced shall not be retained because of nitrosamines if the operator of the establishment makes adjustments in the processing of the product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department. However, if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of the product. All tests of pumped bacon for nitrosamines under this paragraph (b)(1)(i) shall be made on pumped bacon cooked at 340 degrees F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in a sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 ppb.

(ii) Notwithstanding the provisions of paragraph (b)(1)(i) of this section, sodium nitrite may be used at:

(A) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; or

(B) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the production of botulinum toxin at a level sufficient for the purpose of preventing the production of botulinum toxin.

(C) The Department shall collect samples of bacon from establishments producing under paragraph (b)(1)(ii) of this section and analyze them for the level of nitrosamines. Samples shall be

randomly selected throughout the production of a lot. The actual sampling plans and methods of analysis that are used will result in approximately the same likelihood as under paragraph (b)(1)(i) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10 ppb. In the event of a presumptive positive result, the establishment shall become subject to the provisions of paragraph (b)(1)(i) of this section.

(2) *Immersion cured bacon.* Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(3) *Bacon made with dry curing materials.* With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

(c) Irradiation of meat food and poultry products.

(1) *General requirements.* Meat food and poultry products may be treated to reduce foodborne pathogens and to extend product shelf-life by the use of sources of ionizing radiation as identified in 21 CFR 179.26(a). Official establishments must irradiate meat food and poultry products in accordance with 21 CFR 179.26(b), the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, and the provisions of this section.

(2) *Dosimetry.* Official establishments that irradiate meat food and poultry products must have the following procedures in place:

(i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(ii) Calibration criteria for verifying the accuracy and consistency of any means of measurement (*e.g.*, time clocks and weight scales).

(iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.

(iv) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(v) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).

(vi) Procedures for verifying routine dosimetry, i.e., assuring each production lot receives the total absorbed dose. Establishments may either position one dosimeter at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit in each production lot or use statistically based validation and dose mapping to determine the number and placement of dosimeters in each production lot.

(vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.

(3) *Documentation.* Official establishments that irradiate meat food or poultry products must have the following documentation on premises, available to FSIS:

(i) Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC.

(ii) Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable.

(iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(iv) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(v) A certification by the operator that the irradiation facility personnel will only operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.

(vii) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(4) *Labeling.* (i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph. Unless the word ''Irradiated'' is part of the product name, labels also must bear a statement such as ''Treated with radiation'' or ''Treated by irradiation.'' The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under § 317.2(c)(2) of this chapter.

(ii) For meat food or poultry products that have been irradiated in their entirety, but that are not sold in packages, the required logo must be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. Unless the word ''Irradiated'' is part of the product name, the labeling counter sign, card, or other device also must bear a statement such as ''Treated with radiation'' or ''Treated by irradiation.'' The logo must be placed in conjunction with the required statement, if the statement is used.

(iii) The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.

(iv) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section, provided that such statements are not false or misleading. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation.

[64 FR 72175, Dec. 23, 1999, as amended at 64 FR 72165, Dec. 23, 1999; 65 FR 34391, May 30, 2000; 78 FR 66839, Nov. 7, 2013]

§ 424.23 Prohibited uses.

(a) *Substances that conceal damage or inferiority or make products appear better or of greater value.* No substance may be used in or on any meat if it conceals damage or inferiority or makes the

product appear to be better or of greater value than it is. Therefore:

(1) Paprika or oleoresin paprika may not be used in or on fresh meat, such as steaks, or comminuted fresh meat, such as chopped and formed steaks or patties; or in any other meat consisting of fresh meat (with or without seasoning).

(2) Paprika or oleoresin paprika may be used in or on chorizo sausage and other meat in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.

(3) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausages or any other meat; sulfurous acid and salts of sulfurous acid shall not be used in or on any meat; and niacin or nicotinamide shall not be used in or on fresh meat product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), and calcium propionate, may be used in or on any product, only as provided in 9 CFR Chapter III.

(b) *Nitrates.* Nitrates shall not be used in curing bacon.

[64 FR 72175, Dec. 23, 1999, as amended at 78 FR 14640, Mar. 7, 2013]

PART 430—REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

Sec.

AUTHORITY: 7 U.S.C. 450; 7 U.S.C. 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 68 FR 34224, June 6, 2003, unless otherwise noted.

§ 430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called ''prerequisite'' because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

§ 430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes,* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes.* Establishments must not release into commerce product that contains *L. monocytogenes* or that has been in contact with a food contact surface contaminated with *L. monocytogenes* without first reworking the product using a process that is destructive of *L. monocytogenes.*

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) *Alternative 1.* Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *and* an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with § 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(2) *Alternative 2.* Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *or* an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with § 417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes,* its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) *Alternative 3.* Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) In order to release into commerce product held under this section, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other

prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with § 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with § 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) [Reserved]

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

[68 FR 34224, June 6, 2003, as amended at 80 FR 35188, June 19, 2015]

PART 431—THERMALLY PROCESSED, COMMERCIALLY STERILE PRODUCTS

Sec.

AUTHORITY: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 451–472, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 83 FR 25308, May 31, 2018, unless otherwise noted.

§ 431.1 Definitions.

Abnormal container. A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

Acidified low acid product. A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

Bleeders. Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

Canned product. A meat or poultry food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term ''product'' as used in this part means ''canned product.''

Closure technician. The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this part and designated by the establishment to perform such examinations.

Code lot. All production of a particular product in a specific size container marked with a specific container code.

Come-up time. The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

Critical factor. Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

Headspace. That portion of a container not occupied by the product.

(1) *Gross headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (*i.e.,* the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) *Net headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

Hermetically sealed containers. Airtight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) *Rigid container.* A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm^2) (*i.e.,* normal firm finger pressure).

(2) *Semirigid container.* A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm^2) (*i.e.,* normal firm finger pressure).

(3) *Flexible container.* A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

Incubation tests. Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

Initial temperature. The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

Low acid product. A canned product in which any component has a pH value above 4.6.

Process schedule. The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

Process temperature. The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

Process time. The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

Processing authority. The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this part.

Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

Retort. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

Seals. Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

Shelf stability. The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

Thermal process. The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

Venting. The removal of air from a retort before the start of process timing.

Water activity. The ratio of the water vapor pressure of the product to the

vapor pressure of pure water at the same temperature.

§ 431.2 Containers and closures.

(a) *Examination and handling of empty containers.* (1) Empty containers, closures, and flexible pouch roll stock must be evaluated by the establishment to ensure that they are free of structural defects and damage that may affect product or container integrity. Such an examination should be based on a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock must be stored, handled, and conveyed in such a manner that will prevent damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers must be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans)*—(1) *Visual examinations.* A closure technician must visually examine the double seams formed by each closing machine head. When seam defects (*e.g.*, cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, must be taken. In addition to the double seams, the entire container must be examined for product leakage or obvious defects. A visual examination must be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, must be recorded. Visual examinations must be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations must be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.* Teardown examinations of double seams formed by each closing machine head must be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head must be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, must be promptly recorded by the closure technician. The establishment must have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end must be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures must be used in teardown examinations of double seams:

(i) *Dimensional measurement.* One of the following two methods must be employed for dimensional measurements of the double seam.

(A) *Micrometer measurement.* (*1*) For cylindrical containers, measure the following dimensions (Figure 1 to § 431.2) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

(*i*) Double seam length—W;

(*ii*) Double seam thickness—S;

(*iii*) Body hook length—BH; and

(*iv*) Cover hook length—CH.

(*2*) Maximum and minimum values for each dimensional measurement must be recorded by the closure technician.

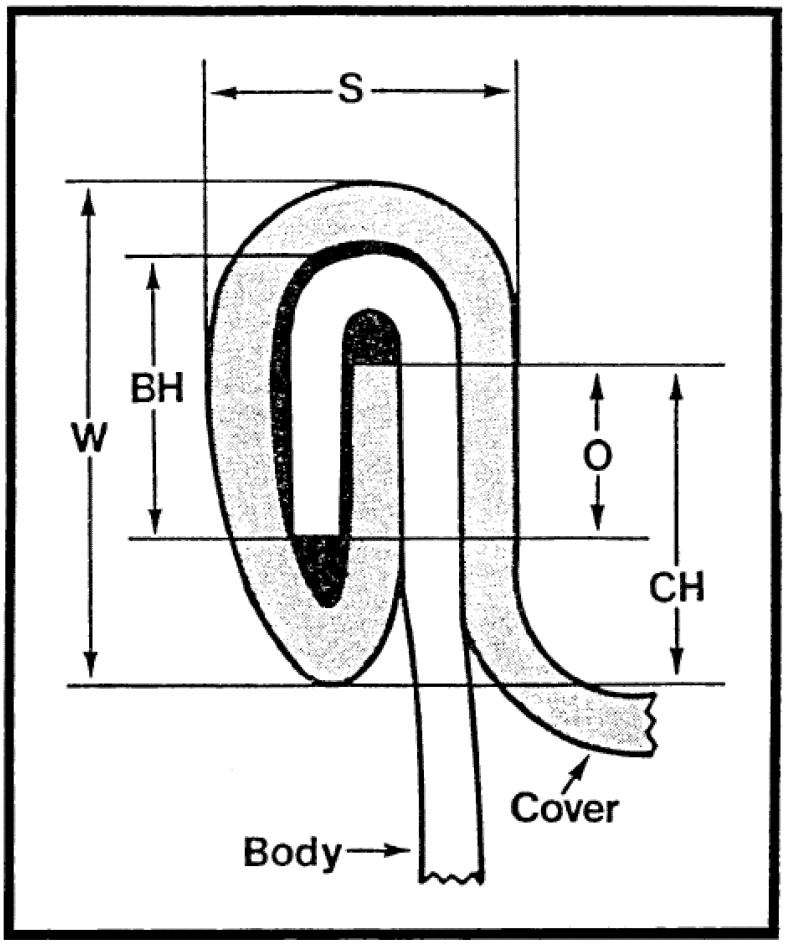


Figure 1 to § 431.2—Micrometer Measurement of Cylindrical Containers

(B) *Seamscope or seam projector.* Required measurements of the seam include thickness, body hook, and overlap.

(ii) *Seam thickness.* Seam thickness must be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, must be used to obtain the required measurements.

(iii) *Seam tightness.* Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined must be stripped to assess the degree of wrinkling.

(iv) *Side seam juncture rating.* Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook must be stripped to examine the cover hook droop at the juncture for containers having side seams.

(v) *Examination of noncylindrical containers.* Examination of noncylindrical containers (*e.g.*, square, rectangular,

''D''-shaped, and irregularly-shaped) must be conducted as described in paragraphs (b)(2)(i), (ii), (iii), and (iv) of this section except that the required dimensional measurements must be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers*—(1) *Visual examinations.* A closure technician must visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine must be taken and recorded. In addition to the closures, the entire container must be examined for defects. Visual examinations must be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations must be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests.* Depending upon the container and closure, tests must be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine must be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, must be promptly recorded by the closure technician. The establishment must have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(d) *Closure examinations for semi-rigid and flexible containers*—(1) *Heat seals*—(i) *Visual examinations.* A closure technician must visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, must be taken and recorded. In addition to examining the heat seals, the entire container must be examined for product leakage or obvious defects. Visual examinations must be performed before and after the thermal processing operation and with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken must be promptly recorded.

(ii) *Physical tests.* Tests determined by the establishment as necessary to assess container integrity must be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests must be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure must be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, must be recorded.

(2) *Recording.* Double seams on semirigid or flexible containers must be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer must also be made and recorded.

(e) *Container coding.* Each container must be marked with a permanent, legible, identifying code mark. The mark must, at a minimum, identify in code the product (unless the product name is lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) *Handling of containers after closure.* (1) Containers and closures must be protected from damage which may cause defects that are likely to affect

the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closure of containers and initiation of thermal processing must be 2 hours unless data are available from the establishment's processing authority demonstrating that an alternative time period is safe and will not result in product spoilage.

§ 431.3 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment must have a process schedule (as defined in § 431.1) for each canned meat or poultry product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment must be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements must be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority must amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, must be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.* (1) Prior to the processing of canned product for distribution in commerce, the establishment must provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules must be maintained on file by the establishment. Upon request by Program employees, the establishment must make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment must provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors must not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

§ 431.4 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule must be measured, controlled, and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) *General.* (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible containers, and to some extent semirigid containers, during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and

(2) Retort reel speed.

(c) *Hydrostatic retorts.* (1) Chain or conveyor speed.

(2) [Reserved]

(d) *Steam/air retorts.* (1) Steam/air ratio; and

(2) Heating medium flow rate.

§ 431.5 Operations in the thermal processing area.

(a) *Posting of processes.* Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, must be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information must be available to the thermal processing system operator and the inspector.

(b) *Process indicators and retort traffic control.* A system for product traffic control must be established to prevent product from bypassing the thermal processing operation. Each basket, crate, or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, must be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles must be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts must be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) *Initial temperature.* The initial temperature of the contents of the coldest container to be processed must be determined and recorded by the establishment at the time the processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins must be operated to assure that such water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) *Timing devices.* Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time, and retort venting, must be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events must have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices must correspond within 15 minutes to the time of the day recorded on written records required by § 431.7.

(e) *Measurement of pH.* Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) must be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

§ 431.6 Equipment and procedures for heat processing systems.

(a) *Instruments and controls common to different thermal processing systems*—(1) *Indicating temperature devices.* Each retort must be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, must be used as the reference instrument for indicating the process temperature.

(i) *Mercury-in-glass thermometers.* A mercury-in-glass thermometer must have divisions that are readable to 1 °F (or 0.5 °C) and whose scale contains not more than 17 °F/inch (or 4.0 °C/cm) of graduated scale. Each mercury-in-glass thermometer must be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test must be maintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard must be repaired and tested for accuracy before further use, or replaced.

(ii) *Other devices.* Temperature-indicating devices, such as resistance temperature detectors, used in lieu of mercury-in-glass thermometers, must meet known, accurate standards for such devices when tested for accuracy. The records of such testing must be available to FSIS program employees.

(2) *Temperature/time recording devices.* Each thermal processing system must be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy must be equal to or better than 1 °F (or 0.5 °C) at the process temperature. The temperature recording chart should be adjusted to agree with, but must never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment must be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers must have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism must be accurate.

(i) *Chart-type devices.* Devices using charts must be used only with the correct chart. Each chart must have a working scale of not more than 55 °F/inch (or 12 °C/cm.) within a range of 20 °F (or 11 °C) of the process temperature. Chart graduations must not exceed 2 °F degrees (or 1 °C) within a range of 10 °F (or 5 °C) of the process temperature. Multipoint plotting chart-type devices must print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The frequency of recording should not exceed 1-minute intervals.

(ii) *Other devices.* Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

(3) *Steam controllers.* Each retort must be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) *Air valves.* All air lines connected to retorts designed for pressure processing in steam must be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle.

(5) *Water valves.* All retort water lines that are intended to be closed during a process cycle must be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle.

(b) *Pressure processing in steam*—(1) *Common to batch still, batch agitating, continuous rotary retorts, and hydrostats*—(i) *Basic requirements.* The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices must be installed either within the retort shell or in external wells attached to the retort. External wells must be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for the external wells must emit steam continuously during the entire thermal processing period.

(ii) *Steam inlet.* The steam inlet to each retort must be large enough to provide steam for proper operation of the retort, and must enter at a point(s) to facilitate air removal during venting.

(iii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment must have on

file documentation that the mufflers do not impede the removal of air from the retort. Such documentation must consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information must be made available to Program employees for review.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices and hydrostatic retorts, must have a ⅛ inch (or 3 mm) or larger openings and must be wide open during the entire process, including the come-up time. All bleeders must be arranged so that the retort operator can observe that they are functioning properly. For horizontal retorts, batch agitating retorts, and continuous rotary retorts, bleeders must be located within approximately 1 foot (or 30 cm) of the outmost locations of containers at each end along the top of the retort. Additional bleeders must be located not more than 8 feet (2.4 m) apart along the top. This information must be maintained on file by the establishment and made available to Program employees for review. Vertical retorts must have at least one bleeder opening located in the portion of the retort opposite the steam inlet. Hydrostatic retorts must have bleeder openings ¼ inch (or 6 mm) or larger which are to be located in the steam chamber(s) opposite the point of steam entry. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort.

(2) *Batch still retorts*—(i) *Crate supports.* Vertical still retorts with bottom steam entry must employ bottom retort crate supports. Baffle plates must not be used in the bottom of retorts.

(ii) *Steam spreader.* Perforated steam spreaders, if used, must be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts must be equipped with perforated steam spreaders that extend the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information must be maintained on file by the establishment and made available to Program employees for review.

(iii) *Condensate removal.* In retorts having a steam inlet above the level of the lowest container, a bleeder must be installed in the bottom of the retort to remove condensate. The condensate bleeder must be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder must be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems must be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system must be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(iv) *Stacking equipment*—(A) *Equipment for holding or stacking containers in retorts.* Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers in the retort must be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle must have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(B) *Divider plates.* Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment must have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation must be in the form of heat distribution data or documentation from a processing authority. This information

must be made available to Program employees for review.

(v) *Vents.* (A) Vents must be located in that portion of the retort opposite the steam inlet and must be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents must be controlled by a gate, plug cock, or other full-flow valve which must be fully opened to permit rapid removal of air from retorts during the venting period.

(B) Vents must not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold must be controlled by a gate, plug cock, or other full-flow valve and the manifold must be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge must not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts must lead to the atmosphere. The manifold header must not be controlled by a valve and must be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(C) Some typical installations and operating procedures are described below. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation must be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information must be maintained on file by the establishment and made available to Program employees for review.

(D) For crateless retort installations, the establishment must have heat distribution data or other documentation from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information must be maintained on file by the establishment and made available to Program employees for review.

(E) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

(*1*) *Venting horizontal retorts.* (*i*) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

Figure 1 to § 431.6 - Equipment and Procedures for Heat Processing Systems

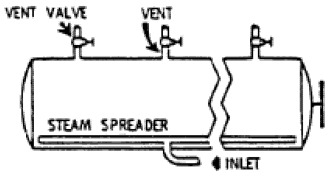


Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to atmosphere. The end vents must not be more than 2 1/2 feet (or 75 cm) from ends of retort.

Venting method (Figure 1): Vent valves must be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*ii*) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

Figure 2 to § 431.6 - Equipment and Procedures for Heat Processing Systems

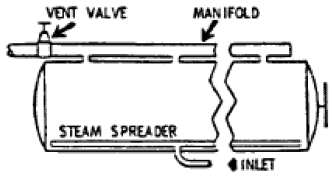


Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2 1/2 feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2 1/2 inches (6.4 cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm).

Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve must be wide open for at least 6 minutes and to at least 225 °F (or 107 °C) or for at least 8 minutes and to at least 220 °F (or 104.5 °C).

(*iii*) Venting through water spreaders.

Figure 3 to § 431.6 - Equipment and Procedures for Heat Processing Systems

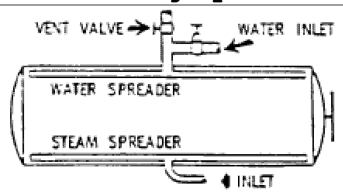


Figure 3.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2 1/2 inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1 1/2 inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length, 2 inches (or 5 cm). The number of holes must be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent must be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*iv*) Venting through a single 2½ inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

Figure 4 to § 431.6 - Equipment and Procedures for Heat Processing Systems

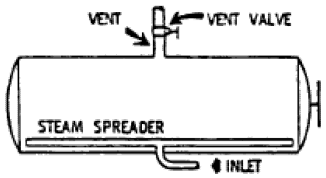


Figure 4.

Specifications (Figure 4): A 2 1/2 inch (6.4 cm) vent equipped with a 2 1/2 inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve must be wide open for at least 4 minutes and to at least 220 °F (or 104.5 °C).

(*2*) *Venting vertical retorts.* (*i*) Venting through a 1½ inch (3.8 cm) overflow.

Figure 5 to § 431.6 - Equipment and Procedures for Heat Processing Systems

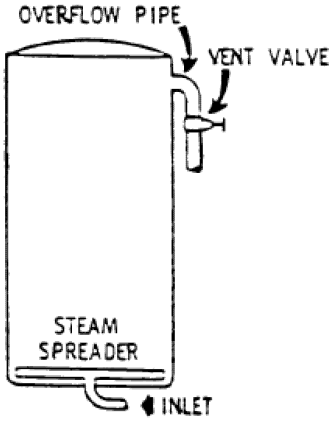


Figure 5.

Specifications (Figure 5): A 1 1/2 inch (3.8 cm) overflow pipe equipped with a 1 1/2 inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8 m) of 1 1/2 inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve must be wide open for at least 4 minutes and to at least 218 °F (or 103.5 °C), or for at least 5 minutes and to at least 215 °F (or 101.5 °C).

(*ii*) Venting through a single 1 inch (2.5 cm) side or top vent.

Figures 6 and 7 to § 431.6 - Equipment and Procedures for Heat Processing Systems

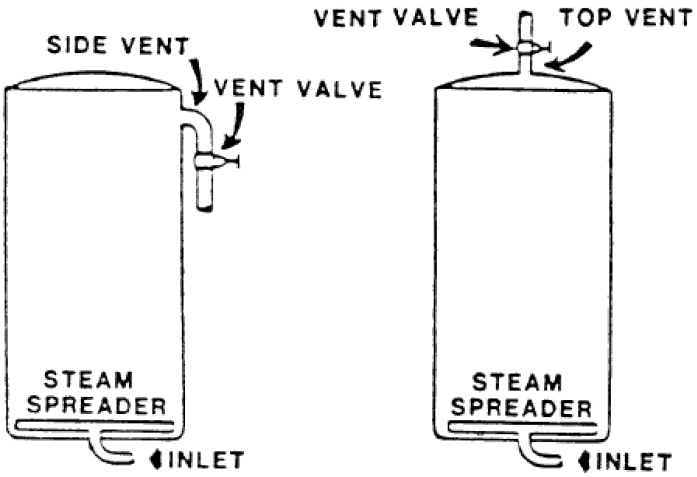


Figure 6 Figure 7

Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve must be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(3) *Batch agitating retorts*—(i) *Venting and condensate removal.* The air in the retort must be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure must be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain must be opened to remove steam condensate from the retort. A bleeder must be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder

must be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder must be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems must be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system must be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(ii) *Retort or reel speed timing.* The retort or reel speed must be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed must be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer must be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(4) *Continuous rotary retorts*—(i) *Venting and condensate removal.* The air in the retort must be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure must be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain must be opened to remove steam condensate from the retort. A bleeder must be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder must be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder must be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems must be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system must be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(ii) *Retort speed timing.* The rotational speed of the retort must be specified in the process schedule. The speed must be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed must be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(5) *Hydrostatic retorts*—(i) *Basic requirements.* The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, indicating temperature devices must be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one indicating temperature device must be located in each hydrostatic water leg so that it

can accurately measure water temperature and be easily read. The temperature/time recorder probe must be installed either within the steam dome or in a well attached to the dome. Each probe must have a 1/16 inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes must be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) *Steam inlet.* The steam inlets must be large enough to provide steam for proper operation of the retort.

(iii) *Bleeders.* Bleeder openings ¼ inch (or 6 mm) or larger must be located in the steam chamber(s) opposite the point of steam entry. Bleeders must be wide open and must emit steam continuously during the entire process, including the come-up time. All bleeders must be arranged in such a way that the operator can observe that they are functioning properly.

(iv) *Venting.* Before the start of processing operations, the retort steam chamber(s) must be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing must be kept on file at the establishment and made available to Program employees for review.

(v) *Conveyor speed.* The conveyor speed must be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed must be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed must be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(vi) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment must have documentation that the mufflers do not impede the removal of air from the retort. Such documentation must consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information must be maintained on file by the establishment and made available to Program employees for review.

(c) *Pressure processing in water*—(1) *Common to batch still and agitating retorts*—(i) *Basic requirements.* The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section.

(ii) *Pressure recording device.* Each retort must be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort must be kept on file at the establishment and made available to Program employees for review.

(iv) *Drain valve.* A non-clogging, water-tight drain valve must be used. Screens must be installed over all drain openings.

(2) *Batch still retorts*—(i) *Temperature device bulbs and probes.* The indicating temperature device bulbs or probes must be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe must be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe must extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe must be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe must

be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers must have filter systems to ensure a supply of clean, dry air.

(ii) *Crate supports.* A bottom crate support must be used in vertical retorts. Baffle plates must not be used in the bottom of the retort.

(iii) *Stacking equipment.* For filled flexible containers and, where applicable, semi-rigid containers, stacking equipment must be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on one another during the thermal process.

(iv) *Water level.* There must be a means of determining the water level in the retort during operation (*i.e.*, by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water must cover the top layer of containers during the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or water sprays, the water level must be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods must be provided. The retort operator must check and record the water level at intervals to ensure it meets the specified processing parameters.

(v) *Air supply and controls.* In both horizontal and vertical still retorts, a means must be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry must be controlled by an automatic pressure control unit. A non-return valve must be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure must be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it must be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution data or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review.

(vi) *Water recirculation.* When a water recirculation system is used for heat distribution, the water must be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader must be uniformly distributed. The suction outlets must be protected with screens to keep debris from entering the recirculation system. The pump must be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(vii) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(3) *Batch agitating retorts*—(i) *Temperature device bulbs and probes.* The indicating temperature device bulb or

probe must extend directly into the water without a separable well or sleeve. The recorder/controller probe must be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) *Stacking equipment.* All devices used for holding product containers (*e.g.*, crates, trays, divider plates) must be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(iii) *Water level.* There must be a means of determining the water level in the retort during operation (*i.e.*, by using a gauge, electronic sensor, or sight glass indicator). Water must completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods must be provided. The retort operator must check and record the adequacy of the water level with sufficient frequency to ensure it meets the specified processing parameters.

(iv) *Air supply and controls.* Retorts must be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry must be controlled by an automatic pressure control unit. A non-return valve must be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure must be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it must be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution data or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review.

(v) *Retort or reel speed timing.* The retort or reel speed timing must be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed must be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer must be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(vi) *Water recirculation.* If a water recirculation system is used for heat distribution, it must be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader must be uniformly distributed. The suction outlets must be protected with screens to keep debris from entering the recirculation system. The pump must be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution data or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and

made available to Program employees for review.

(vii) *Cooling water entry*. In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) *Pressure processing with steam/air mixtures in batch retorts*—(1) *Basic requirements*. The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes must be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) *Recording pressure controller*. A recording pressure controller must be used to control the air inlet and the steam/air mixture outlet.

(3) *Circulation of steam/air mixtures*. A means must be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The efficiency of the circulation system must be documented by heat distribution data or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review. The circulation system must be checked to ensure its proper functioning and must be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference must be made to the equipment manufacturer for details of installation, operation, and control.

(e) *Atmospheric cookers*—(1) *Temperature/time recording device*. Each atmospheric cooker (*e.g.*, hot water bath) must be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) *Heat distribution*. Each atmospheric cooker must be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker must be kept on file by the establishment and made available to Program employees for review.

(f) *Other systems*. All other systems not specifically delineated in this section and used for the thermal processing of canned product must be adequate to produce shelf-stable products consistently and uniformly.

(g) *Equipment maintenance*. (1) Upon installation, all instrumentation and controls must be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system must be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing must be checked by the establishment for leaks. Defective valves must be repaired or replaced as needed.

(4) Vent and bleeder mufflers must be checked and maintained or replaced by the establishment to prevent any reduction in bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule must be developed and implemented to assure that the holes are maintained at their original size.

(6) Records must be kept on all maintenance items that could affect the adequacy of the thermal process. Records must include the date and type of maintenance performed and the person conducting the maintenance.

(h) *Container cooling and cooling water*. (1) Potable water must be used for cooling except as provided for in paragraphs (h)(2) and (3) of this section.

(2) Cooling canal water must be chlorinated or treated with a chemical having a bactericidal effect equivalent to chlorination. There must be a measurable residual of the sanitizer in the

water at the discharge point of the canal. Cooling canals must be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused must be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, must be constructed and installed so that they can be cleaned and inspected. In addition, the establishment must maintain, and make available to Program employees for review, information on at least the following:

(i) System design and construction;

(ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;

(iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and

(iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) *Post-process handling of containers.* Containers must be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like must be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on moving conveyors. All post-process container handling equipment should be kept clean so there is no buildup of microorganisms on surfaces in contact with the containers.

§ 431.7 Processing and production records.

At least the following processing and production information must be recorded by the establishment: Date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of § 431.4 regarding the control of critical factors must be recorded. In addition, where applicable, the following information and data must also be recorded:

(a) *Processing in steam*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder must be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required for batch still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) *Continuous rotary retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed must be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and temperature recorder(s) must be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) must be observed and recorded at the time the first container enters the retort and thereafter as specified in § 431.305(b)(3)(v).

(4) *Hydrostatic retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time

steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device must be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments must be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, must be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) *Processing in water*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder must be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) *Processing in steam/air mixtures.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder must be read at the same time at least once during process timing and the observed temperatures recorded.

(d) *Atmospheric cookers*—(1) *Batch-type systems.* For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) *Continuous-type systems.* Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

§ 431.8 Record review and maintenance.

(a) *Process records.* Charts from temperature/time recording devices must be identified by production date, container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in § 431.7. Each entry on a record must be made at the time the specific event occurs, and the recording individual must sign or initial each record form. No later than 1 working day after the actual process, the establishment must review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, must be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart must be made available to Program employees for review.

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems must be designed and operated in a manner that will ensure compliance

with the applicable requirements of § 431.7.

(c) *Container closure records.* Written records of all container closure examinations must specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records must be signed or initialed by the container closure technician and must be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart must be made available to Program employees for review.

(d) *Distribution of product.* Records must be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) *Retention of records.* Copies of all processing and production records required in § 431.7 must be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

§ 431.9 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it must be considered a deviation in processing.

(b) Deviations in processing (or process deviations) must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbial contamination; or,

(2) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(3) Paragraph (c) of this section.

(c) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Deviations identified in-process.* If a deviation is noted at any time before the completion of the intended process schedule, the establishment must:

(i) Immediately reprocess the product using the full process schedule; or

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 431.3(a) and (b) and is filed with the inspector in accordance with § 431.3(c); or

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment must provide the inspector the following:

(A) A complete description of the deviation along with all necessary supporting documentation;

(B) A copy of the evaluation report; and

(C) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (c)(1)(iii) of this section must not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product must be set aside for further evaluation in accordance with paragraphs (c)(1)(iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product must be handled in accordance with paragraphs (c)(1)(iii) and (iv) of this section or in accordance with the following procedures:

(A) *Emergency stops.* (*1*) When retort jams or breakdowns occur during the processing operations, all containers

must be given an emergency still process (developed per § 431.3(b)) before the retort is cooled or the retort must be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown must be removed and either reprocessed, repacked and reprocessed and or destroyed. Product to be destroyed must be handled as ''U.S. Inspected and Condemned,'' as defined in § 301.2 of this chapter, or as ''U.S. Condemned,'' as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(*2*) The time the retort reel stopped and the time the retort is used for an emergency still retort process must be noted on the temperature/time recording device and entered on the other production records required in § 431.7.

(B) *Temperature drops*. When the retort temperature drops below the temperature specified in the process schedule, the reel must be stopped and the following actions must be taken:

(*1*) For temperature drops of less than 10 °F (or 5.5 °C) either:

(*i*) All containers in the retort must be given an emergency still process (developed per § 431.3(b)) before the reel is restarted;

(*ii*) Container entry to the retort must be prevented and an emergency agitating process (developed per § 431.3(b)) must be used before container entry to the retort is restarted; or

(*iii*) Container entry to the retort must be prevented and the reel restarted to empty the retort. The discharged containers must be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed must be handled as ''U.S. Inspected and Condemned,'' as defined in § 301.2 of this chapter, or as ''U.S. Condemned,'' as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(*2*) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort must be given an emergency still process (developed per § 431.3(b)). The time the reel was stopped and the time the retort was used for a still retort process must be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 431.7. Alternatively, container entry to the retort must be prevented and the reel restarted to empty the retort. The discharged containers must be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed must be handled as ''U.S. Inspected and Condemned,'' as defined in § 301.2 of this chapter, or as ''U.S. Condemned,'' as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(2) *Deviations identified through record review*. Whenever a deviation is noted during review of the processing and production records required by § 431.8(a) and (b), the establishment must hold the product involved and the deviation must be handled in accordance with paragraphs (c)(1)(iii) and (iv) of this section.

(d) *Process deviation file*. The establishment must maintain full records regarding the handling of each deviation. Such records must include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records must be maintained in a separate file or in a log that contains the appropriate information. The file or log must be retained in accordance with § 431.8(e) and must be made available to Program employees upon request.

§ 431.10 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) An HACCP plan for canned product that addresses hazards associated with microbiological contamination;

(2) An FSIS-approved total quality control system;

(3) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(4) Paragraph (b) of this section.

(b) Procedures for handling finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Incubation of shelf stable canned product*—(i) *Incubator.* The establishment must provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature.* The incubation temperature must be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature must be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) must be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation.* Shelf stable product requiring incubation includes:

(A) Low acid products as defined in § 431.1; and

(B) Acidified low acid products as defined in § 431.1.

(iv) *Incubation samples.* (A) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment must select at least one container for incubation.

(B) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment must select at least one container per 1,000 for incubation.

(C) Only normal-appearing containers must be selected for incubation.

(v) *Incubation time.* Canned product requiring incubation must be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (b)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance.* Designated establishment employees must visually check all containers under incubation each working day and the inspector must be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment must record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment must retain such records, along with copies of the temperature/time recording charts, in accordance with § 431.8(d).

(vii) *Abnormal containers.* The finding of abnormal containers (as defined in § 431.1) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping.* No product must be shipped from the establishment before the end of the required incubation period. An establishment wishing to ship product prior to the completion of the required incubation period must submit a written proposal to the District Office. Such a proposal must include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the District Office, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) [Reserved]

(c) *Container condition*—(1) *Normal containers.* Only normal-appearing containers must be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to program employees.

(2) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment must inform the inspector, and the affected code lot(s) must not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

§ 431.11 Personnel and training.

All operators of thermal processing systems specified in § 431.6 and container closure technicians must be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

§ 431.12 Recall procedure.

Establishments must prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure must be made available to Program employees for review.

PART 439—ACCREDITATION OF NON-FEDERAL CHEMISTRY LABORATORIES

Sec.

AUTHORITY: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 73 FR 52196, Sept. 9, 2008, unless otherwise noted.

§ 439.1 Definitions.

(a) *Accreditation*—Determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation specified in this part, for the presence and amount of all four food chemistry analytes (protein, moisture, fat, and salt); or a determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation in this part, for the presence and amount of a specified chemical residue of any one of several classes of chemical residues. A laboratory may hold more than one accreditation.

(b) *Accredited laboratory*—A non-Federal analytical laboratory that has met the requirements for accreditation specified in this Part and, therefore, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

(c) *Accredited Laboratory Program (ALP)*—The FSIS program in which non-Federal laboratories are accredited as eligible to perform analyses on official regulatory samples of raw or processed meat and poultry products, and through which a check sample program for quality assurance is conducted.

(d) *Chemical residue misidentification*—see ''Correct chemical residue identification'' definition.

(e) *Coefficient of variation (CV)*—The standard deviation of a distribution of analytical values multiplied by 100 and divided by the mean of those values.

(f) *Comparison mean*—The average result, for a sample, obtained from all submitted results that have a large deviation measure of zero. When only two laboratories perform the analysis and the large deviation measure is not zero, alternative procedures for establishing a comparison mean may be employed by FSIS. For purposes of computing the comparison mean, a laboratory's ''result'' for a food chemistry analyte is the obtained analytical value; a laboratory's ''result'' for a chemical residue is the logarithmic transformation of the obtained analytical value.

(g) *Correct chemical residue identification*—Reporting by a laboratory of the presence and analytical value of a chemical residue that was included in

the ALP check sample above the minimum reporting level. Failure of a laboratory to report the presence of such a chemical residue is considered a misidentification. In addition, reporting the presence of and analytical value for a residue that was not included in the ALP check sample above the minimum reporting level is considered a misidentification.

(h) *CUSUM*—A class of statistical procedures for assessing whether or not a process is ''in control.'' Each CUSUM value is constructed by accumulating incremental values obtained from observed results of the process, and then determined to either exceed or fall within acceptable limits for that process. The initial CUSUM values for each laboratory whose application for accreditation is accepted are set at zero. The CUSUM values are reset to zero at the beginning of each year; that is, the CUSUM values associated with the first maintenance check sample each year are set equal to the CUSUM increment for that sample. The four CUSUM procedures are:

(1) Positive systematic laboratory difference CUSUM (CUSUM–P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

(2) Negative systematic laboratory difference CUSUM (CUSUM–N)—monitors how consistently an accredited laboratory gets numerically smaller results than the comparison mean;

(3) Variability CUSUM (CUSUM–V)—monitors the average ''total deviation'' (i.e., the combination of the random fluctuations and systematic differences) between an accredited laboratory's results and the comparison mean; and

(4) Individual large deviation CUSUM (CUSUM–D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

(i) *Food chemistry*—For the purposes of part 439, ''food chemistry'' will refer to analysis of raw or processed meat or poultry products for the analytes moisture, protein, fat, and salt. All four analytes must be determined when a food chemistry analysis is conducted, unless otherwise advised by the ALP.

(j) *Individual large deviation*—An analytical result that differs from the sample comparison mean by more than would be expected assuming normal laboratory variability.

(k) *Initial accreditation check sample*—A sample provided by the ALP to a non-Federal laboratory to determine whether the laboratory's analytical capability meets the standards for granting accreditation.

(l) *Inter-laboratory accreditation maintenance check sample*—A sample provided by FSIS to an accredited laboratory to assist in determining whether the laboratory is maintaining acceptable levels of analytical capability.

(m) *Large deviation measure*—A measure that quantifies an unacceptably large difference between a laboratory's analytical result and the sample comparison mean.

(n) *Minimum proficiency level* (MPL)—The minimum concentration of a residue at which an analytical result will be used to assess a laboratory's quantification capability. This concentration is an estimate of the smallest concentration for which the average coefficient of variation (CV) for reproducibility (i.e., combined within and between laboratory variability) does not exceed 20 percent.

(o) *Minimum reporting level* (MRL)—The number such that if any obtained analytical value for a residue in a check sample or official sample equals or exceeds this number, then the residue is reported together with the obtained analytical value.

(p) *Official sample*—A sample selected by an inspector or inspection service employee in accordance with FSIS procedures for regulatory use.

(q) *Probation*—The period commencing with official notification to an accredited laboratory that its check sample results no longer satisfy the performance requirements specified in this rule, and ending with official notification that accreditation either is fully restored, is suspended, or is revoked.

(r) *QA* (See Quality assurance recovery).

(s) *QC* (See Quality control recovery).

(t) *Quality assurance (QA) recovery*—The ratio of a laboratory's analytical value for a check sample residue to the

established level of the analyte in the check sample, multiplied by 100. As dictated by the procedures for the analyte, the analytical value may be adjusted prior to the recovery computation.

(u) *Quality control (QC) recovery*—The ratio of a laboratory's analytical value of a quality control standard to the established level of the analyte in the standard, multiplied by 100. As dictated by the procedures for the analyte, the analytical value may be adjusted prior to the recovery computation.

(v) *Refusal of accreditation*—An action taken by FSIS when a laboratory that is applying for accreditation is denied the accreditation.

(w) *Responsibly connected*—Any individual, or entity, that is a partner, officer, director, manager, or owner of 10 percent or more of the voting stock of the applicant or recipient of accreditation or an employee in a managerial or executive capacity or any employee who conducts or supervises the chemical analysis of FSIS official samples.

(x) *Revocation of accreditation*—An action taken by FSIS against a laboratory, removing the laboratory's right to analyze official samples.

(y) *Standardizing constant*—A number that results from a mathematical adjustment to the ''standardizing value'' and is used to compute the standardized difference for a check sample result. The number takes into consideration the expected variance of the difference between the accredited or applying laboratory's result(s) and the comparison mean for a sample, the standardizing value, the correlation and number of repeated results by a laboratory on a sample, and the number of laboratories that analyzed a sample.

(z) *Standardized difference*—The quotient of the difference between a laboratory's result on a sample and the comparison mean of the sample divided by the standardizing constant.

(aa) *Standardizing value*—A number representing the performance standard deviation of an individual result. The number is given, or computed by, the information provided in Tables 1 and 2 to this paragraph (aa).

TABLE 1 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR FOOD CHEMISTRY

[By product class and analyte]

Product/class	Moisture	Protein [1]	Fat [1]		Salt [1]		
			<12.5%	≥12.5%	<1%	1–4%	≥4% [2]
Cured Pork/ Canned Ham	0.50	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Ground Beef	0.71	0.060 ($X^{0.65}$)	N/A	0.35 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Other Meat Products	0.57	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Poultry Products	0.57	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22

[1] The standardizing value is either the value given in the table or is computed by the formula set forth in the table, where X is the comparison mean of the sample. Standardizing values are provided for different percentages of fat and salt as indicated in the table.

[2] For dry salami and pepperoni products.

TABLE 2 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Standardizing value [3]
Chlorinated Hydrocarbons: [1]	
Aldrin	0.20
Benzene Hexachloride	0.20
Chlordane	0.20
Dieldrin	0.20
DDT	0.20
DDE	0.20
TDE	0.20
Endrin	0.20
Heptachlor	0.20
Heptachlor Epoxide	0.20
Lindane	0.20
Methoxychlor	0.20
Toxaphene	0.20

TABLE 2 TO PARAGRAPH (aa)—STANDARDIZING VALUES FOR CHEMICAL RESIDUES—Continued

Class of residues	Standardizing value [3]
Hexachlorobenzene	0.20
Mirex	0.20
Nonachlor	0.20
Polychlorinated Biphenyls:	0.20
Arsenic [2]	0.25
Sulfonamides [2]	0.25
Volatile Nitrosamine [2]	0.25

[1] Laboratory statistics are computed over all results (excluding PCB results), and for specific chemical residues.

[2] Laboratory statistics are only computed for specific chemical residues.

[3] The standardizing value of all initial accreditation and probationary check samples computations is 0.15.

(bb) *Suspension of accreditation*—Action taken by FSIS against a laboratory that temporarily removes the laboratory's right to analyze official samples. Suspension of accreditation ends when accreditation either is fully restored or is revoked.

(cc) *Systematic laboratory difference*—A comparison of one laboratory's results with the comparison mean for samples that show, on average, a consistent relationship. A laboratory that is reporting, on average, numerically greater results than the comparison mean has a positive systematic laboratory difference. Conversely, numerically smaller results indicate a negative systematic laboratory difference.

(dd) *Variability*—Random fluctuations in a laboratory's processes that cause its analytical results to deviate from a true value.

(ee) *Variance*—The expected average of the squared differences of sample results from an expected sample mean.

§ 439.5 Applications for accreditation.

(a) Application for accreditation shall be made on designated paper or electronic forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory. The forms shall be sent to the ALP or may be submitted electronically when so provided for by FSIS. The application shall specify the kinds of accreditation that are wanted by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked may reapply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

(b) At the time that an Application for Accreditation is filed with the ALP, the management of a laboratory shall, for each accreditation sought, submit a check, bank draft, or money order in the amount specified in 9 CFR 391.5, made payable to the U.S. Department of Agriculture, along with the completed application for the accreditation(s). When so provided for by FSIS, electronic transfer of funds may be accepted.

(c) Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid will be nonrefundable and will be credited to the account from which the expenses of the laboratory accreditation program are paid.

(d) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5 for each accreditation held. Bills are payable upon receipt by check, bank draft, or money order made payable to the U.S. Department of Agriculture and become delinquent 30 days from the date of the bill.

(e) Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid will be nonrefundable and will be credited to the account from which the expenses of the ALP are paid.

§ 439.10 Criteria for obtaining accreditation.

(a) Analytical laboratories may be accredited for the analyses of food chemistry analytes, as defined in § 439.1 of this part, or a specific chemical residue or a class of chemical residues in raw or processed meat and poultry products.

(b) Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below. For food chemistry accreditation, the requirements must be satisfied for all four analytes.

(c) This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples.

(d) To obtain FSIS accreditation, an analytical laboratory must:

(1) Be supervised by a person holding, at a minimum, a bachelor's degree in chemistry, food science, food technology, or a related field.

(i) For food chemistry accreditation, the supervisor must also have one year's experience in food chemistry analysis, or equivalent qualifications, as determined by the Administrator.

(ii) For chemical residue accreditation, either the supervisor or the analyst assigned to analyze the sample must also have three years' experience determining analytes at or below part

per million levels, or equivalent qualifications, as determined by the Administrator.

(2) Demonstrate an ability to achieve quality assurance levels that are within acceptable limits for systemic laboratory difference, variability, and individual large deviations, in the analyte category for which accreditation is sought, using analytical procedures designated by the FSIS ALP as being acceptable. An applying laboratory will successfully demonstrate these capabilities for:

(i) Food chemistry if its results from a 36 check sample accreditation study each satisfy the criteria presented in paragraph (e) of this section.

(ii) Chemical residues if its analytical results for each specific chemical residue provided in a check sample accreditation study containing a minimum of 14 check samples satisfy the criteria presented in paragraph (e) of this section, including criteria for QA and QC recovery and for residue identification. In addition, if the laboratory is requesting accreditation for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria. [Conformance to criteria in paragraph (e) of this section will only be determined when six or more analytical results with associated comparison means at or above the logarithm of the minimum proficiency level are available.]

(3) Round all check sample statistical computations to the nearest tenth, except where otherwise noted.

(4) Complete a second set of the requisite number of check samples if the results of the first set of check samples do not meet the criteria for obtaining accreditation.

(i) The second set of check samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. The second set of food chemistry check samples will be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory.

(ii) If the results of the second set of check samples do not meet the criteria for obtaining accreditation, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

(5) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

(6) Pay the accreditation fee by the date required.

(e) *Quality assurance levels*—(1) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed the following:

(i) For food chemistry, 0.73 minus the product of 0.17 and the standard deviation of the standardized differences; and

(ii) For chemical residues, 1.67 (2.00 if there are less than 12 analytical results) minus the product of 0.29 and the standard deviation of the standardized differences.

(2) *Variability:* The estimated standard deviation of the standardized difference must not exceed the following:

(i) For food chemistry, 1.15; and

(ii) For chemical residues, a computed limit that is a function of the number of analytical results used in the computation of the standard deviation, and of the amount of variability.

(3) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual samples must be less than 5.0. A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5 and otherwise a measure equal to 1–(2.5/d).

(4) For residue analyses, the following additional quality assurance requirements must be met.

(i) *QA recovery:* The average of the QA recoveries of the individual check sample analytical results must lie within ranges established by FSIS.

(ii) *QC recovery:* All QC recoveries must lie within ranges established by FSIS. Supporting documentation must be made available to FSIS upon request.

(iii) *Correct identification:* There must be correct identification of all chemical residues in all samples.

§ 439.20 Criteria for maintaining accreditation.

(a) To maintain accreditation, an analytical laboratory must fulfill the requirements of paragraphs (b) through (i) of this section.

(b) *Official samples.* (1) An accredited laboratory must expeditiously report analytical results, in the analyte category for which accreditation was granted, of official samples on designated forms to the Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, P.O. Box 6085, Athens, GA 30604 (for U.S. Postal Service delivery), or Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, 950 College Station Road, Athens, GA 30605 (for commercial carrier delivery). When so provided for by FSIS, analytical results may be reported to the Data Center Staff by facsimile at (706) 546–3589, or electronically. The Federal inspector at any establishment may assign the analysis of official samples to an FSIS laboratory if, in the inspector's judgment, there are delays in receiving test results on official samples from an accredited laboratory.

(2) Every QC recovery associated with reporting of official samples must lie within ranges established by FSIS. Supporting documentation must be made available to FSIS upon request.

(c) *Records.* An accredited laboratory must:

(1) Maintain laboratory quality control records for the most recent three years that samples have been analyzed under this Program.

(2) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent three years that samples have been analyzed under this Program.

(3) Maintain in a secure electronic format or in a standards book, which is preferably a permanently bound book with sequentially numbered pages, all records, readings, and calculations for standard solutions. All entries are to be dated and signed by the analyst immediately upon completion of the entry, and by the supervisor, or in the absence of the supervisor by the supervisor's designee, before use of the standard solution but no later than within one week. The standards book is to be retained for three years after the last recorded entry.

(4) Maintain records and supervisor approvals of recoveries, and of instrument maintenance and calibration. The records are to be retained for three years after the last recorded entry.

(5) As provided in paragraph (f) of this section, records should be available for review by any duly authorized representative of the Secretary of Agriculture, including ALP personnel or their designees.

(d) *Check samples.* (1) An accredited laboratory must analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within three weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(2) Results must be those of the accredited laboratory. Analyses of maintenance check samples shall not be contracted out by the accredited laboratory.

(3) As provided by the requirements in paragraph (h) of this section, a check sample report will be considered complete only if laboratories report all analytes present in the check sample for the analyte category in which accreditation was granted.

(e) *Corporate changes.* The ALP must be informed within 30 days of any change of address or in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(f) *On-site review.* An accredited laboratory must permit any duly authorized representative of the Secretary to perform both announced and unannounced on-site laboratory reviews of facilities and records, both hard copy and electronic, during normal business hours, and to copy any records pertaining to the laboratory's participation in the ALP.

(g) *Analytical procedures.* An accredited laboratory must use analytical procedures designated by the FSIS ALP as being acceptable.

(h) *Quality assurance levels.* (1) An accredited laboratory must demonstrate an ability to maintain quality assurance levels that are within acceptable limits for systematic laboratory difference, variability, and individual large deviations in the analysis of

interlaboratory check samples for the analyte category for which accreditation was granted. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results from interlaboratory accreditation maintenance check samples satisfy the criteria presented in this paragraph (h). All statistical computations are to be rounded to the nearest tenth, except where otherwise noted.

(2) In addition, a laboratory accredited for a specific chemical residue or a chemical residue class:

(i) Must satisfy criteria presented in this paragraph for chemical residue recoveries and proper identification;

(ii) Must demonstrate the maintenance of its capabilities by reporting its analytical results for each specific chemical residue found above the minimum proficiency level; and

(iii) Must, if accredited for the analysis of chlorinated hydrocarbons, obtain analytical results that collectively satisfy the criteria.

(3) *Systematic laboratory difference:* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine two CUSUM values, designated as CUSUM–P and CUSUM–N.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The average of the standardized differences of the analytical results within the sample, divided by a constant, is used in place of a single standardized difference to determine the CUSUM–P (or CUSUM–N) value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) Positive systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM–P increment for the sample.

(*1*) The CUSUM–P increment for food chemistry, as defined in §439.1 of this part, is set equal to:

2.0, if the standardized difference is greater than 2.4,

−2.0, if the standardized difference is less than −1.6, or

the standardized difference minus 0.4, if the standardized difference lies between −1.6 and 2.4, inclusive.

(*2*) The CUSUM–P increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 2.5,

−2.0, if the standardized difference is less than −1.5, or

the standardized difference minus 0.5, if the standardized difference lies between −1.5 and 2.5, inclusive.

(B) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM–P increment to the last previously computed CUSUM–P value. If this computation yields a value smaller than 0, the new CUSUM–P value is set equal to 0.

(C) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed:

(*1*) 5.2 for food chemistry.

(*2*) 4.8 for chemical residues.

(iii) Negative systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM–N increment for the sample.

(*1*) The CUSUM–N increment for food chemistry is set equal to:

2.0, if the standardized difference is greater than 1.6,

−2.0, if the standardized difference is less than −2.4, or

the standardized difference plus 0.4, if the standardized difference lies between −2.4 and 1.6, inclusive.

(*2*) The CUSUM–N increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 1.5,

−2.0, if the standardized difference is less than −2.5, or

the standardized difference plus 0.5, if the standardized difference lies between −2.5 and 1.5, inclusive.

(B) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM–N increment from the last previously computed CUSUM–N value. If this computation yields a value

smaller than 0, the new CUSUM–N value is set equal to 0.

(C) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed:

(*1*) 5.2 for food chemistry.

(*2*) 4.8 for chemical residues.

(4) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The square root of the sum of the within sample variance and the average standardized difference of the sample, divided by a constant, is used in place of the absolute value of the standardized difference to determine the CUSUM–V value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) The variability value is computed and designated as follows:

(A) Determine the CUSUM–V increment for the sample. The CUSUM increment is set equal to the larger of −0.4 or the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

(B) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM–V increment to the last previously computed CUSUM–V value. If this computation yields a value less than 0, the new CUSUM–V value is set equal to 0.

(C) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(5) *Large deviations:* The large deviation measure of the accredited laboratory's result for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.

(i) A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)$.

(ii) The large deviation value is computed and evaluated as follows:

(A) Determine the CUSUM–D increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(B) Compute the new CUSUM–D value. The new CUSUM–D value is obtained by adding, algebraically, the CUSUM–D increment to the last previously computed CUSUM–D value. If this computation yields a value less than 0, the new CUSUM–D value is set equal to 0.

(C) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(6) For chemical residues:

(i) Each QC recovery must lie within ranges established by FSIS.

Supporting documentation must be made available to FSIS upon request.

(ii) Not more than one residue misidentification may be made in any two consecutive check samples.

(iii) Not more than two residue misidentifications may be made in any eight consecutive check samples.

(i) *Fees.* An accredited laboratory must pay the required accreditation fee when it is due.

(j) *Probation.* An accredited laboratory must meet the following requirements if placed on probation pursuant to § 439.51 of this part:

(1) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS laboratory by certified mail or private carrier or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analyte(s). Mailing expenses will be paid by FSIS.

(2) Analyze a set of check samples similar to those used for initial accreditation, and submit the analytical results to FSIS within three weeks of receipt of the samples.

(3) Satisfy criteria for accreditation check samples specified in § 439.10 of this part.

§ 439.50 Refusal of accreditation.

Upon a determination by the Administrator, a laboratory will be refused accreditation for the following reasons:

(a) A laboratory will be refused accreditation for failure to meet the requirements of § 439.5 or § 439.10 of this part.

(b) A laboratory will be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analytes, all official samples that have not been analyzed as of the notification of a loss of accreditation.

(c) A laboratory will be refused accreditation if the laboratory or any individual or entity responsibly connected with the laboratory has been convicted of, or is under indictment for, or has charges on an information brought against them in a Federal or State court concerning any of the following violations of law:

(1) Any felony.

(2) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(3) Any misdemeanor based upon a false statement to any governmental agency.

(4) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.51 Probation of accreditation.

Upon a determination by the Administrator, a laboratory will be placed on probation for the following reasons:

(a) If the laboratory fails to complete more than one interlaboratory accreditation maintenance check sample analysis as required by § 439.20(d) of this part within 12 consecutive months, unless written permission is granted by the Administrator.

(b) If the laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this part.

§ 439.52 Suspension of accreditation.

The accreditation of a laboratory will be suspended if the laboratory or any individual or entity responsibly connected with the laboratory is indicted or has charges on information brought against them in a Federal or State court for any of the following violations of law:

(a) Any felony.

(b) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(c) Any misdemeanor based upon a false statement to any governmental agency.

(d) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.53 Revocation of accreditation.

The accreditation of a laboratory will be revoked for the following reasons:

(a) An accredited laboratory that is accredited to perform analysis under §§ 439.5, 439.10 and 439.20 of this part will have its accreditation revoked for failure to meet any of the requirements of § 439.20 of this part, except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this part and it has not failed during the 12 months preceding its failure to meet the criteria, it shall be placed on probation, but if it has failed at any time during those 12 months, its accreditation will be revoked.

(b) An accredited laboratory will have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(1) Altered any official sample or analytical finding; or

(2) Substituted any analytical result from any other laboratory and represented the result as its own.

(c) An accredited laboratory will have its accreditation revoked if the laboratory or any individual or entity responsibly connected with the laboratory is convicted in a Federal or State court of any of the following violations of law:

(a) Any felony.

(b) Any misdemeanor based upon acquiring, handling, or distributing of

unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(c) Any misdemeanor based upon a false statement to any governmental agency.

(d) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.60 Notification and hearings.

Accreditation of any laboratory will be refused, suspended, or revoked under the conditions previously described in this Part 439. The owner or operator of the laboratory will be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension, or revocation decision. An oral hearing will be granted if there is any dispute of material fact joined in such responsive statement. The proceeding will be conducted thereafter in accordance with the applicable rules of practice, which will be adopted for the proceeding. Any such refusal, suspension, or revocation will be effective upon the receipt by the laboratory of the notification and will continue in effect until final determination of the matter by the Administrator.

PART 441—CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 66 FR 1771, Jan. 9, 2001, unless otherwise noted.

§ 441.10 Retained water.

(a) Raw livestock, poultry, and fish carcasses and parts will not be permitted to retain water resulting from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected in accordance with a written protocol, that any water retained in the carcasses or parts is an unavoidable consequence of the process used to meet applicable food safety requirements.

(b) Raw livestock, poultry, and fish carcasses and parts that retain water from post-evisceration processing and that are sold, transported, offered for sale or transportation, or received for transportation, in commerce, must bear a statement on the label in prominent letters and contiguous to the product name or elsewhere on the principal display panel of the label stating the maximum percentage of water that may be retained (*e.g.*, ''up to X% retained water,'' ''less than X% retained water,'' ''up to X% water added from processing''). The percent water statement need not accompany the product name on other parts of the label. Raw livestock and poultry carcasses and parts that retain no water may bear a statement that no water is retained.

(c)(1) An establishment subject to paragraph (a) of this section must maintain on file and available to FSIS its written data-collection protocol. The protocol must explain how data will be collected and used to demonstrate the amount of retained water in the product covered by the protocol that is an unavoidable consequence of the process used to meet specified food safety requirements.

(2) The establishment must notify FSIS as soon as it has a new or revised protocol available for review by the Agency. Within 30 days after receipt of this notification, FSIS may object to or require the establishment to make changes in the protocol.

(d) Expected elements of a protocol for gathering water retention data:

(1) *Purpose statement.* The primary purpose of the protocol should be to determine the amount or percentage of water absorption and retention that is unavoidable using a particular chilling system while achieving the regulatory pathogen reduction performance standard for *Salmonella* as set forth in the PR/HACCP regulations (9 CFR 310.25(b), 381.94(b)) and the time/temperature requirements set forth in 9 CFR 381.66. Additional purposes that could be included are determining chilling system efficiency and evaluating product quality.

(2) *Type of washing and chilling system used by the establishment.* Any post-evisceration washing or chilling processes that affect water retention levels in and microbial loads on raw products should be described. For poultry establishments, the main chiller types, identified by the mechanism used to transport the birds through the chiller or to agitate the water in the chiller, are the drag-through, the screw type, and the rocker-arm type.

(3) *Configuration and any modifications of the chiller system components.* A description of chiller-system configurations and modifications should be provided. The description should include the number and type of chillers in a series and arrangements of chilling system components, and the number of evisceration lines feeding into a chiller system. If there is a pre-chilling step in the process, its purpose and the type of equipment used should be accurately described. Any mechanical or design changes made to the chilling equipment should be described.

(4) *Special features in the chilling process.* Any special features in the chilling process, such as antimicrobial treatments, should be described. Also, the length and velocity of the dripping line should be described, as well as the total time allowed for dripping. Any special apparatus, such as a mechanism for squeezing excessive water from chilled birds, should be explained.

(5) *Description of variable factors in the chilling system.* The protocol should describe variable factors that affect water absorption and retention. In poultry processing, such factors are typically considered to be the time in chiller water, the water temperature, and agitation. The protocol should consider air agitation, where applicable. Additional factors that may affect water absorption and retention are scalding temperature and the pressure or amount of buffeting applied to birds by feather removal machinery, and the resultant loosening of the skin. Another factor that should be considered is the method used to open the bird for evisceration.

(6) *Standards to be met by the chilling system.* For example, the chilling system may be designed simply to achieve a reduction in temperature of ready-to-cook poultry to less than 40 °F within the time limit specified by the regulations, or in less time. As to the standard for pathogen minimization, the *Salmonella* pathogen reduction standards, as set forth in the PR/HACCP final rule, have been suggested. Although there is not yet an applicable *Salmonella* standard for turkeys, establishments are free to adopt practicable criteria for use in gathering data on turkeys under the protocols here suggested. Additional microbiological targets, such as *E. coli* or *Campylobacter* levels, or reductions in numbers of other microorganisms, may also be used.

(7) *Testing methods to be employed.* The protocol should detail the testing methods to be used both for measuring water absorption and retention and for sampling and testing product for pathogen reductions. The protocol should call for water retention and pathogen reduction tests at various chilling equipment settings and chilling time-and-temperature combinations. The method to be used in calculating water absorption and retention should be reproducible and statistically verifiable. With respect to the pathogen-reduction aspect of the testing, FSIS recommends the methods used for *E. coli* and *Salmonella* testing under the PR/HACCP regulations. The number of samples, the type of samples, the sampling time period, and the type of testing or measurement should be included in the protocol.

(8) *Reporting of data and evaluation of results.* The protocol should explain how data obtained are to be reported and summarized. The criteria for evaluating the results and the basis for conclusions to be drawn should be explained.

(9) *Conclusions.* The protocol should provide for a statement of what the data obtained demonstrate and what conclusions were reached.

[66 FR 1771, Jan. 9, 2001, as amended at 80 FR 75616, Dec. 2, 2015]

PART 442—QUANTITY OF CONTENTS LABELING AND PROCEDURES AND REQUIREMENTS FOR ACCURATE WEIGHTS

Sec.
442.1 Quantity of contents labeling
442.2 Definitions and procedures for determining net weight compliance
442.3 Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection
442.4 Testing of scales
442.5 Handling of failed product

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 73 FR 52192, Sept. 9, 2008, unless otherwise noted.

§ 442.1 Quantity of contents labeling.

This part prescribes the procedures to be followed for determining net weight compliance and prescribes the reasonable variations allowed from the declared net weight on the labels of immediate containers of products in accordance with 9 CFR 317.2(c)(4), 317.2(h), and 381.121.

§ 442.2 Definitions and procedures for determining net weight compliance.

(a) For the purpose of § 442.1 of this part, the reasonable variations allowed, and the definitions and the procedures to be used, in determining net weight and net weight compliance are presented in the National Institute of Standards and Technology (NIST) Handbook 133, ''Checking the Net Contents of Packaged Goods,'' Fourth Edition, January 2005, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of NIST Handbook 133 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, 732 N. Capitol Street, NW., Washington, DC, 20401. You may contact the Government Printing Office Toll-Free at 1–866–512–1800 or go to: *http://bookstore.gpo.gov*. You may inspect a copy of NIST Handbook 133 at the FSIS Docket Room, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue, SW., Room 2534, Washington, DC 20250. You can contact the FSIS Docket room by calling 202–720–0344 or 202–720–3813. The NIST Handbook 133 is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to:*http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) The following NIST Handbook 133 requirements are not incorporated by reference.

CHAPTER 2—BASIC TEST PROCEDURE—GRAVIMETRIC TESTING

2.3 Basic Test Procedure—Tare Procedures—*Wet Tare*
2.3 Basic Test Procedure—Moisture Allowances—*What moisture allowance is used with wet tare when testing packages bearing a USDA seal of inspection?*
2.4 Borax

CHAPTER 3—TEST PROCEDURES—FOR PACKAGES LABELED BY VOLUME

3.5 Mayonnaise and Salad Dressing
3.7 Pressed and Blown Glass Tumblers and Stemware
3.8 Volumetric Test Procedures for Paint, Varnish, and Lacquers—Non Aerosol
3.9 Testing Viscous Materials—Such as Caulking Compounds and Pasters
3.10 Peat Moss
3.11 Mulch and Soils Labeled by Volume
3.12 Ice Cream Novelties
3.13 Fresh Oysters Labeled by Volume
3.14 Determining the Net Contents of Compressed Gas Cylinders
3.15 Volumetric Test Procedures for Packaged Firewood with a Labeled Volume of 133 L (4 Cu Ft) or Less
3.16 Boxed Firewood
3.17 Crosshatched Firewood
3.18 Bundles and Bags of Firewood

CHAPTER 4—TEST PROCEDURES—PACKAGES LABELED BY COUNT, LINEAR MEASURE, AREA, THICKNESS, AND COMBINATIONS OF QUANTITIES

4.5 Paper Plates and Sanitary Paper Products
4.6 Special Test Requirements for Packages Labeled by Linear or Square Measure (Area)
4.7 Polyethylene sheeting
4.8 Packages Labeled by Linear or Square (Area) Measure
4.9 Bailer Twine—Test Procedure for Length
4.10 Procedure for Checking the Area Measurement of Chamois Appendix C Glossary—wet tare

§ 442.3 Scale requirements for accurate weights, repairs, adjustments, and replacements after inspection.

(a) All scales used to determine the net weight of meat and poultry products sold or otherwise distributed in commerce in federally inspected meat and poultry establishments will be installed, maintained, and operated in a manner that ensures accurate weights. Such scales shall meet the applicable requirements contained in National Institute of Standards and Technology (NIST) Handbook 44, ''Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices,'' 1999 Edition, November 1988, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited here will be published in the FEDERAL REGISTER. Copies may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402. The incorporation information also is available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) All scales used to determine the net weight of meat or poultry products sold or otherwise distributed in commerce or in States designated under section 301(c) of the Federal Meat Inspection Act and section 5(c) of the Poultry Products Inspection Act shall be of sufficient capacity to weigh the entire unit or package.

(c) No scale will be used at a federally inspected establishment to determine the net weight of meat or poultry products unless it has been found upon test and inspection, as specified in NIST Handbook 44 to provide accurate weight. If a scale is inspected or tested and found to be inaccurate, or if any repairs, adjustments, or replacements are made to a scale, it shall not be used until it has been reinspected and retested by a USDA official, or a State or local government weights and measures official, or a State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook 44. If a USDA inspector has put a ''Retain'' tag on a scale, the tag can only be removed by a USDA inspector. As long as the tag is on the scale, it shall not be used.

§ 442.4 Testing of scales.

(a) The operator of each official establishment that weighs meat or poultry food products will cause such scales to be tested for accuracy in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more frequent tests may be required and verified by an authorized USDA program official.

(b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures authority or from a State registered or licensed scale repair firm or person, or shall have alternative documented procedures showing that the scale has been tested for accuracy in accordance with the requirements of NIST Handbook 44.

§ 442.5 Handling of failed product.

Any lot of product that is found to be out of compliance with net weight requirements upon testing in accordance with the methods prescribed in § 442.2 of this subchapter shall be handled as follows:

(a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section in accordance with the requirements of this part.

(b) A lot tested outside an official establishment and found not to comply with net weight requirements must be reweighed and remarked with a proper net weight statement, provided that such reweighing and remarking will not deface, cover, or destroy any other marking or labeling required under this subchapter, and the net quantity of contents is shown with the same prominence as the most conspicuous feature of a label.

PART 500—RULES OF PRACTICE

Sec.

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 64 FR 66546, Nov. 29, 1999, unless otherwise noted.

§ 500.1 Definitions.

(a) A ''regulatory control action'' is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

(b) A ''withholding action'' is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

(c) A ''suspension'' is an interruption in the assignment of program employees to all or part of an establishment.

§ 500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:

(1) Insanitary conditions or practices;

(2) Product adulteration or misbranding;

(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or

(4) Inhumane handling or slaughtering of livestock.

(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.

(c) An establishment may appeal a regulatory control action, as provided in §§ 306.5 and 381.35 of this chapter.

§ 500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;

(2) The establishment does not have a HACCP plan as specified in § 417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§ 416.11–416.12 of this chapter;

(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;

(5) The establishment violated the terms of a regulatory control action;

(6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.

(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

§ 500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

(a) The HACCP system is inadequate, as specified in § 417.6 of this chapter, due to multiple or recurring noncompliances;

(b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§ 416.13 through 416.16 of this chapter;

(c) The establishment has not maintained sanitary conditions as prescribed in §§ 416.2–416.8 of this chapter due to multiple or recurring noncompliances;

(d) The establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with § 310.25(a) or § 381.94(a) of this chapter;

(e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in § 310.25(b) or § 381.94(b) of this chapter.

§ 500.5 Notification, appeals, and actions held in abeyance.

(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:

(1) State the effective date of the action(s),

(2) Describe the reasons for the action(s),

(3) Identify the products or processes affected by the action(s),

(4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and

(5) Advise the establishment that it may appeal the action as provided in §§ 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in § 500.4 of this part will:

(1) State the type of action that FSIS may take;

(2) Describe the reason for the proposed action;

(3) Identify the products or processes affected by the proposed action;

(4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and

(5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

(c) An establishment may appeal the withholding action or suspension, as provided in §§ 306.5 and 381.35 of this chapter.

(d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.

(e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

§ 500.6 Withdrawal of inspection.

The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H because:

(a) An establishment produced and shipped adulterated product;

(b) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;

(c) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;

(d) An establishment did not maintain sanitary conditions;

(e) An establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results as prescribed in § 310.25(a) or § 381.94(a) of this chapter;

(f) [Reserved]

(g) An establishment did not slaughter or handle livestock humanely;

(h) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or

(i) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

[64 FR 66546, Nov. 29, 1999, as amended at 79 FR 49637, Aug. 21, 2014]

§ 500.7 Refusal to grant inspection.

(a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:

(1) Does not have a HACCP plan as required by part 417 of this chapter;

(2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;

(3) Has not demonstrated that adequate sanitary conditions exist in the

establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;

(4) Has not demonstrated that livestock will be handled and slaughtered humanely; or

(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

(b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

§ 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.

(b) FSIS will provide written notification that:

(1) Explains the reason for rescinding or refusing the approval;

(2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and

(3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.

(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H.

SUBCHAPTER F—MANDATORY INSPECTION OF FISH OF THE ORDER SILURIFORMES AND PRODUCTS OF SUCH FISH

PART 530—GENERAL REQUIREMENTS; DEFINITIONS

Sec.
530.1 General.
530.2 FSIS organization for fish inspection.
530.3 Access to establishments.

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 530.1 General.

(a) The regulations in this subchapter provide for the inspection of Siluriformes fish and fish products. The inspection and regulations are intended to prevent the sale, transportation, offer for sale or transportation, or receipt for transportation, in commerce of any fish or fish product that is capable of use as human food and is adulterated or misbranded at the time of the sale, transportation, offer for sale or transportation, or receipt for transportation.

(b) Fish as defined in this subchapter are amenable to the Act, including, as the Administrator may determine, to provisions of the Act in which other amenable species are named, except where the Act specifically excludes the provisions from applicability to fish.

§ 530.2 FSIS organization for inspection of fish and fish products.

The Food Safety and Inspection Service, U.S. Department of Agriculture, administers an inspection program for fish and fish products. The organization of FSIS and the principal offices of FSIS and their functions are described, and organizational terms defined, in 9 CFR part 300, subchapter A of this chapter. Section 300.3 lists the FSIS district offices and the geographic areas of the districts.

§ 530.3 Access to establishments.

The provisions of 9 CFR 300.6 apply to fish processing establishments and related industries as they do to other establishments subject to the FMIA.

PART 531—DEFINITIONS

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 531.1 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

Act. The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 106 Stat. 4499, 119 Stat. 2166, 122 Stat. 1369, 122 Stat. 2130, 21 U.S.C., sec. 601 *et seq.*).

Adulterated. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(iv) If it bears or contains any color additive which is unsafe within the

meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: Provided, That an article which is not deemed adulterated under paragraphs (2)(ii), (iii), or (iv) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefore; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Amenable species. A species that is, and whose products are, subject to the Act and regulations promulgated under the Act, except as the Act may provide.

Animal food. Any article intended for use as food for dogs, cats, or other animals, derived wholly, or in part, from the carcass or parts or products of the carcass of any amenable species, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Feeds for amenable species manufactured from processed by products of amenable species.

Applicant. Any person who requests inspection service, exemption, or other authorization under the regulations.

Biological residue. Any substance, including metabolites, remaining in fish at time of slaughter or in any of their tissues after slaughter as the result of treatment or exposure of the fish to a pesticide, organic or inorganic compound, hormone, hormone like substance, anthelmintic, or other therapeutic or prophylactic agent.

Capable of use as human food. This term applies to any carcass or part or product of a carcass of any fish unless it is denatured or otherwise identified as required by § 540.3 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; *e.g.*, barbels or fins in their natural state.

Carcass. All parts, including viscera, of any slaughtered livestock.

Commerce. Commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

Consumer package. Any container in which a fish product is enclosed for the purpose of display and sale to household consumers.

Container. Any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

Dead fish. The body of a fish that has died otherwise than by slaughter.

Dying or diseased fish. Fish affected by any of the conditions for which the fish are required to be condemned under part 539 or other regulations in this subchapter.

Edible. Intended for use as human food.

Farm-raised. Grown under controlled conditions, within an enclosed space, as on a farm.

Federal Food, Drug, and Cosmetic Act. The Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Firm. Any partnership, association, or other unincorporated business organization.

Fish. (1) For the purposes of this subchapter, any fish of the order Siluriformes, whether live or dead.

(2) The skeletal muscle tissue of fish. As applied to products of fish of the order Siluriformes, this term has a meaning comparable to that of ''meat'' in the meat inspection regulations (9 CFR 301.2).

Fish byproduct. Any fish part capable of use as human food, other than the skeletal muscle tissue, that has been derived from one or more fish.

Fish food product. Any article capable of use as human food that is made wholly or in part from any fish or part thereof; or any product that is made wholly or in part from any fish or part thereof, excepting those exempted from definition as a fish product by the Administrator in specific cases or by a regulation in this subchapter; upon a determination that they contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the fish food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to ensure that the fish meat or other portions of such carcasses contained in such articles are not adulterated, and that such articles are not represented as fish food products.

Fish product. Any fish or fish part; or any product that is made wholly or in part from any fish or fish part, except for those exempted from definition as a fish product by the Administrator in a regulation in this subchapter. Except where the context requires otherwise (*e.g.*, in part 540 of this subchapter), this term is limited to articles capable of use as human food.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

Immediate container. The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Inedible. Adulterated, uninspected, or not intended for use as human food.

''Inspected and passed'' or ''U.S. Inspected and Passed'' or ''U.S. Inspected and Passed by Department of Agriculture'' (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Labeling. All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

Misbranded. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (7)(ii) of this definition unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of fish food and fish products excluding labeling and packaging materials as covered in part 541 of this subchapter.

Official certificate. Any certificate prescribed by the regulations in this subchapter for issuance by an inspector or other person performing official functions under the Act.

Official device. Any device prescribed by the regulations in part 312 of this subchapter for use in applying any official mark.

Official establishment. Any slaughtering, cutting, boning, fish product canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in this section, where inspections are authorized to be conducted as prescribed in part 557 of this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article, fish, or fish product under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for fish products.

Person. Any individual, firm, or corporation.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for purposes of the Act and the regulations in this subchapter as under the Federal, Drug, and Cosmetic Act.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Process authority. A person or organization with expert knowledge in fish production process control and relevant regulations. This definition does not apply to § 548.6 of this subchapter or to subpart G of part 318 of this chapter.

Process schedule. A written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. This definition does not apply to § 548.6 of this subchapter or to subpart G of part 318 of this chapter.

Producer. Any person engaged in the business of growing farm-raised fish.

Product. Any carcass, fish, fish product, or fish food product, capable of use as human food.

Program. The organizational unit within the Department having the responsibility for carrying out the provisions of the Act.

Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

Slaughter. With respect to fish, intentional killing under controlled conditions.

State. Any State of the United States or the Commonwealth of Puerto Rico.

Territory. Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States.

U.S. Condemned. This term means that the fish, part, or product of fish so identified was inspected and found to be adulterated and is condemned.

U.S. Detained. This term applies to fish, fish products, and other articles which are held in official custody in accordance with section 402 of the Act (21 U.S.C. 672), pending disposal as provided in the same section 402.

U.S. Retained. This term means that the fish, part, or product of fish so identified is held for further examination by an inspector at an official establishment to determine its disposal.

United States. The States, the District of Columbia, and the Territories of the United States.

[80 FR 75616, Dec. 2, 2015]

PART 532—REQUIREMENTS FOR INSPECTION

Sec.

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 532.1 Establishments requiring inspection; other inspection.

(a) No establishment may process or prepare fish, fish parts, or fish products capable of use as human food, or sell, transport, or offer for sale or transportation in commerce any of these articles without inspection under these regulations, except as expressly exempted in § 532.3.

(b) Inspection under the regulations is required at:

(1) Every establishment, except as provided in the regulation on exemption of retail operations (§ 532.3), in which any fish or fish products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food.

(2) Every establishment, except as provided in the regulation on exemption of retail operations (§ 532.3), within any State or organized territory which is designated pursuant to section 301 of the Act (21 U.S.C. 661), at which any fish or fish products are processed for use as human food solely for distribution within that State or territory.

(3) Except as provided in the regulation on exemption of retail operations (§ 532.3), every establishment designated by the administrator under

section 301 of the Act (21 U.S.C. 661) as one producing adulterated fish products which would clearly endanger the public health.

(4) *Coverage of fish and fish products processed in official establishments.* All fish and fish products prepared in an official establishment must be inspected, handled, processed, marked, and labeled as required by the regulations.

(5) *Other inspection.* Periodic inspections may be made of:

(i) The records of all persons engaged in the business of hatching, feeding, growing, or transporting fish between premises where fish are bred, hatcheries, and premises where fish are grown, and from these premises to processing establishments.

(ii) Exempted retail establishments to determine that those establishments are operating in accordance with these regulations.

§ 532.2 Application for inspection; information to be furnished; grant or refusal of Inspection; conditions for receiving inspection; official numbers and inspection; assignment and authorities of Program employees.

(a) Application for inspection is as required by 9 CFR 304.1.

(b) Information to be furnished is as required by 9 CFR 304.2(a), (b), and (c)(1). Conditions for receiving inspection, including having written Sanitation SOPs, HACCP plans and written recall procedures, are as required by 9 CFR 304.3.

(c) Official numbers; inauguration of inspection; withdrawal of inspection; reports of violation. The requirements for assignment of official numbers, inauguration of inspection, withdrawal of inspection, and reports of violations at fish processing establishments are as required by part 305 of this chapter for meat establishments.

(d) Assignment and authorities of program employees. The requirements concerning the assignment and authorities of Program employees at fish processing establishments are as required by parts 306 and 307 of this chapter with respect to Program employees at meat establishments.

§ 532.3 Exemption of retail operations.

(a) The exemption in 9 CFR 303.1(d) for operations of types traditionally and usually conducted at retail stores and restaurants applies with respect to fish products as it does with respect to products of other amenable species under the FMIA.

(b) The exemption also applies to the slaughtering of fish conducted at and by the operator of a retail store or restaurant, with respect to live fish purchased by a consumer at the retail store or restaurant, in accordance with the consumer's instructions.

(c) A retail quantity of fish or fish products sold to a household consumer is a normal retail quantity if it does not exceed 75 pounds and the quantity of fish or fish product sold by a retail supplier to a non-household consumer is a normal retail quantity if it does not exceed 150 pounds in the aggregate.

§ 532.4 Inspection at official establishments; relation to other authorities.

(a) Requirements within the scope of the Act with respect to premises, facilities, and operations of any official establishment that are in addition to or different than those made under this subchapter may not be imposed by any State or local jurisdiction except that the State or local jurisdiction may impose recordkeeping and other requirements within the scope of § 550.1 of this subchapter, if consistent with those requirements, with respect to the establishment.

(b) Labeling, packaging, or ingredient requirements in addition to or different than those made under this subchapter, the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act may not be imposed by any State or local jurisdiction with respect to any fish or fish products processed at any official establishment in accordance with the requirements under this subchapter and those Acts.

§ 532.5 Exemption from definition of fish product of certain human food products containing fish.

The following articles contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers to be

products of the fish food products industry. Therefore, the articles are exempted from the definition of ''fish product'' and the requirements of the Act and the regulations that apply to fish products, if they comply with the conditions specified in this section.

(a) Any human food product if:

(1) It contains less than 3 percent raw or 2 percent cooked fish;

(2) The fish ingredients used in the product were prepared under Federal inspection or were inspected under a foreign inspection system approved under § 557.2 of this subchapter and imported in compliance with the Act and the regulations;

(3) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(4) The product is not represented as a fish product. The percentage of cooked fish ingredients must be computed on the basis of the moist, deboned, cooked fish in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) A product exempted under this section will be deemed to be represented as a fish product if the term ''fish'' or a term representing a fish species that is covered by the definition of ''fish'' in part 531 of this subchapter is used in the product name of the product without appropriate qualification.

(c) A product exempted under this section is subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

PART 533—SEPARATION OF ESTABLISHMENT; FACILITIES FOR INSPECTION; FACILITIES FOR PROGRAM EMPLOYEES; OTHER REQUIRED FACILITIES

Sec.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 533.1 Separation of establishments.

Each official establishment shall be separate and distinct from any unofficial establishment and from any other official establishment, except an establishment preparing products under the FMIA, the PPIA, or the EPIA, or under State fish inspection requirements and authorities that are deemed to be at least equal to those provided under the FMIA. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe. An official establishment that is not separate and distinct from another official or unofficial establishment must ensure that no sanitary hazards are created by the lack of separation.

§ 533.2 [Reserved]

§ 533.3 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, must be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the District Manager or the frontline supervisor and must be conveniently located, properly ventilated, and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such facilities are deemed necessary by the frontline supervisor. At the discretion of the Administrator, small establishments requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing must be provided by each establishment.

§ 533.4 Other facilities and conditions to be provided.

When required by the District Manager or the frontline supervisor, each official establishment must provide the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions:

(a) Sufficient light to be adequate for the proper conduct of inspection;

(b) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(c) Receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned and to be marked in a conspicuous manner with the phrase ''U.S. Condemned'' in letters not less than 2 inches high, and, when required by the frontline supervisor, to be equipped in a way that allows the receptacles to be locked or sealed;

(d) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in handling diseased carcasses, for cleaning and sanitizing floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(e) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter;

(f) Docks and receiving rooms, to be designated by the operator of the official establishment, with the frontline supervisor, for the receipt and inspection of fish, fish products, or other products.

(g) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) can be stored. Official certificates shall be kept when not in use in suitable file cabinets. All such lockers and file cabinets shall be equipped for sealing or locking with locks or seals to be supplied by the Department. The keys of such locks shall not leave the custody of Program employees.

§ 533.5 Schedule of operations.

The requirements governing the schedule of operations for fish processing establishments are as required by 9 CFR 307.4 for meat establishments.

§ 533.6 Overtime and holiday inspection service.

The requirements governing overtime and holiday inspection service in 9 CFR 307.5 apply to fish processing establishments.

§ 533.7 Basis of billing for overtime and holiday services.

The requirements for billing and overtime and holiday inspection services are as required by 9 CFR 307.6.

PART 534—PRE-HARVEST STANDARDS AND TRANSPORTATION TO PROCESSING ESTABLISHMENT

Sec.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 534.1 General.

Fish that are harvested for use as human food must have grown and lived under conditions that will not render the fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food.

§ 534.2 Water quality for food fish.

Farmers of fish should monitor the water in which the fish are raised for the presence of suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals that may contaminate fish. FSIS will collect samples of feed, fish, and water from producers, at intervals to be determined by the Administrator, for the purpose of verifying that fish are being raised under conditions that will yield safe, wholesome products.

§ 534.3 Standards for use of drugs in the raising of fish.

New animal drugs that are the subject of an approved new animal drug application (NADA) or abbreviated new animal drug application (ANADA) under section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360b), or a conditional approval under section 571 of the Act (21 U.S.C. 360ccc), or an investigational exemption under section 512(j) of the Act (21 U.S.C. 360b(j)) may be used in the raising of fish. New animal drugs approved under section 512 of the Act may be used in an extra-label manner if such use complies with section 512(a)(4) of the Act and FDA regulations found at 21 CFR part 530.

§ 534.4 Transportation to processing plant.

A vehicle used to transport fish from a producer's premises to a processing establishment must be equipped with vats or other containers for holding the fish. The vats or other containers must be maintained in a sanitary condition. Sufficient water and sufficient oxygen must be provided to the vats that hold the fish to ensure that fish delivered to the processing establishment will not be adulterated. Any fish that are dead, dying, diseased, or contaminated with substances that may adulterate fish products are subject to condemnation at the official fish processing establishments.

PART 537—SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS; NOTIFICATION REGARDING ADULTERATED OR MISBRANDED PRODUCTS

Sec.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 537.1 Basic requirements.

(a)(1) Any official establishment that prepares or processes fish or fish products for human food must comply with the requirements contained in 9 CFR parts 416, Sanitation and 417, Hazard Analysis and Critical Control Point (HACCP) Systems, except as otherwise provided in this subchapter.

(2) For the purposes of 9 CFR part 416, Sanitation; 9 CFR part 417, Hazard Analysis and Critical Control Point (HACCP) Systems; and 9 CFR part 500, Rules of Practice, an ''official establishment'' or ''establishment'' includes a plant that prepares or processes fish or fish products.

§ 537.2 Hazard analysis and HACCP plan.

(a) A fish establishment's hazard analysis shall take into account the food safety hazards that can occur before, during, and after harvest.

(b) The failure of an establishment to develop and implement a hazard analysis and a HACCP plan that comply with this part or to operate in accordance with the requirements of 9 CFR Chapter III, Subchapter E, will render the products produced under these conditions adulterated.

§ 537.3 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded fish product received by or originating from the official establishment has entered commerce, in accordance with the requirements of 9 CFR part 418.

PART 539—MANDATORY DISPOSITIONS; PERFORMANCE STANDARDS RESPECTING PHYSICAL, CHEMICAL, OR BIOLOGICAL CONTAMINANTS

Sec.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.

(a)(1) Carcasses or parts of fish affected by abscesses or lesions, zoonotic and non-zoonotic parasites such as cestodes, or such parasites as digenean trematodes, metacercaria (*Bolbophorus* spp.), yellow grubs (*Clinostomum* spp.), or white grubs (Hysteromorpha spp.) are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(2) Fish affected by Heterophyid intestinal flukes or *Dictophymatidae* nematodes are subject to condemnation unless properly disposed of by the establishment.

(b) Fish affected by diseases, including columnaris (infection by Flavobacterium columnare/*Flexibacter columnaris*) and enteric septicemia of fish (ESC), are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(c) Fish carcasses or parts or fish products that are found to be in a state of spoilage or decomposition are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(d) Fish with unusual gross deformities caused by disease or chemical contamination may not be used for human food.

§ 539.2 Physical, chemical, or biological contaminants.

(a) Fish and fish products that are contaminated with physical matter are subject to official retention and condemnation.

(b) Antibiotic or other drug residues in fish tissues must be within applicable tolerances in 21 CFR part 556 or within an applicable import tolerance established under 21 U.S.C. 360b(a)(6).

(c) Pesticide residues in fish tissues must be within applicable tolerances in 40 CFR part 180.

(d) Fish or fish products containing violative concentrations of drugs or other chemicals are subject to condemnation.

PART 540—HANDLING AND DISPOSAL OF CONDEMNED AND OTHER INEDIBLE MATERIALS

Sec.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 540.1 Dead fish.

(a) With the exception of dead fish that have died en route to an official establishment that have been received with live fish at the official establishment, and that are subject to sorting and disposal at the official establishment, no fish or part of the carcass of fish that died otherwise than by slaughter may be brought onto the premises of an official establishment without advance permission from the FSIS frontline supervisor.

(b) The official establishment shall maintain physical separation between slaughtered fish and the edible parts or products of slaughtered fish and any fish or parts of fish that have died otherwise than by slaughter. Fish or any parts of fish that have died otherwise than by slaughter shall be excluded from any room or compartment in which edible product is prepared, handled, or stored.

§ 540.2 Specimens for educational, research, and other nonfood purposes; permits.

The requirements of 9 CFR 314.9 apply to the handling and release of specimens of condemned or other inedible fish materials.

§ 540.3 Handling and disposal of condemned or other inedible materials.

Condemned or other inedible fish and fish parts shall be separated from edible fish. If not disposed of on the premises of the establishment, the condemned and inedible fish parts shall be conveyed from the official establishment for disposition at a rendering plant, an animal feed manufacturing

establishment, or at another establishment for other non-food use. If not decharacterized by use of approved denaturants or colorings, the inedible materials shall be enclosed in containers that are conspicuously marked to indicate that the contents are condemned or otherwise inedible. The materials may be shipped under company or official seal to a rendering facility or for other inedible processing.

PART 541—MARKS, MARKING AND LABELING OF PRODUCTS AND CONTAINERS

Sec.

AUTHORITY: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 541.1 General.

The marks, devices, and certificates prescribed or referenced in this part are official marks, devices, and certificates for the purposes of the Act respecting fish and fish products. The marks, devices, and certificates shall be used only in accordance with the regulations in this part.

§ 541.2 Official marks and devices to identify inspected and passed fish and fish products.

(a)(1) The official inspection legend required by this part must be shown on all labels for inspected and passed fish and fish products and must be in the following form prescribed in 9 CFR 312.2(b)(1) for inspected and passed products of cattle, sheep, swine, and goats, or in another form to be prescribed by the Administrator, except that it need not be of the size illustrated, if it is of a sufficient size and color to be conspicuously displayed, and readily legible, and in the same proportions of letter size and boldness are maintained as illustrated:

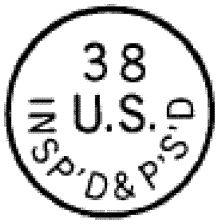
(2) The official inspection legend shall contain the words ''U.S. Inspected and Passed'' or an abbreviation of those words approved by the Administrator.

(b) This official mark must be applied by mechanical means and must not be applied by a hand stamp.

(c)(1) The official inspection legend, or the approved abbreviation of the legend, must be printed on consumer packages and other immediate containers of inspected and passed fish products or on labels to be securely affixed to the containers of the products and may be printed or stenciled on the containers but must not be applied by rubber stamping.

(2) The official inspection legend may also be used for the purposes of marking shipping containers, band labels, and other articles with the approval of the Administrator.

(d) Whole gutted fish carcasses that have been inspected and passed in an official establishment and are intended for sale as whole gutted fish must be marked with the official inspection legend or properly packaged in an immediate container labeled with the official inspection legend and all other required labeling features, that will ensure that the fish carcasses are identified as ''Inspected and Passed'' and will not become misbranded while in commerce. The official inspection legend used for this purpose must be in the form illustrated below or in another form determined by the Administrator:



§ 541.3 Official seals for transportation of products.

The official mark for use in sealing railroad cars, cargo containers, or other means of conveyance as prescribed in part 555 of this subchapter must be the inscription and serial number shown in 9 CFR 312.5 or another official mark approved by the Administrator. Any seal approved by the Administrator for applying the official mark is an official device for the purposes of the Act. The seal must be attached to the means of conveyance only by a Program employee, who shall also affix a ''Warning Tag'' (Form MP–408–3 or similar official form).

§ 541.4 Official export inspection marks, devices, and certificates.

(a) The official export inspection mark for fish required by part 552 of this subchapter must be in the same form as that specified in 9 CFR 312.8(a) or otherwise as prescribed by the Administrator.

(b) The official export certificate for fish and fish products required by part 552 must be in the same form as that prescribed for meat and meat food products in 9 CFR 312.8(b) or otherwise as prescribed by the Administrator.

§ 541.5 Official detention marks and devices.

The official mark for shipments of articles and fish detained under this subchapter is the designation ''U.S. Detained,'' and the official device for applying the mark is the official ''U.S. Detained'' tag (FSIS Form 8400–2) as prescribed in 9 CFR 329.2 or otherwise by the Administrator.

§ 541.7 Labels required; supervision of a Program employee.

(a) *General labeling requirements.* The requirements in part 317, subpart A, of this chapter, governing labels and labeling, safe-handling labeling, abbreviations of official marks, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official inspection marks, filling of containers, relabeling of products, the storage and distribution of labels, and the requirements for packaging materials, apply to fish and fish products.

(b) A country of origin statement on the label of any fish ''covered commodity'' as defined in 7 CFR part 60, subpart A, that is sold by a ''retailer,'' as defined in 7 CFR 60.124, must comply with the requirements of 7 CFR 60.200 and 60.300.

(c) The safe handling instructions required on labels of fish and fish products specified in paragraph (a) of this section shall replace statements that include the terms ''meat'' and ''poultry'' with the following:

(1) In the rationale statement, ''This product was prepared from inspected

and passed fish. Some food products may contain bacteria that could cause illness if the product is mishandled and cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(2) In the labeling statements, ''Keep raw fish separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish. (A graphic illustration of soapy hands under a faucet shall be displayed next to statement.)''

(d)(1) Labels and labeling of fish in the order Siluriformes and the products of those fish must bear the appropriate common or usual names of the fish. For example, among fish in the family Pangasiidae, the labels and labeling for fish of the species *Pangasius bocourti* must bear the term ''basa''; for the species *Pangasius hypophthalmus* or *Pangasionodon hypophthalmus*, ''swai,'' ''tra,'' or ''sutchi.''

(2) The labels and labeling only of fish and fish products within the family Icataluridae may bear the term ''catfish.''

(e) The requirements in part 441 of this chapter, governing water retained from processing in raw meat and poultry, apply to retained water in fish. The requirements in part 442 of this chapter, governing quantity of contents labeling, the testing of scales, and the handling of product that is found to be out of compliance with net weight requirements, apply to fish and fish products.

(1) Packages of frozen or fresh-frozen fish carcasses or parts must be labeled to reflect 100-percent net weight after thawing. The de-glazed net weight must average 100 percent of the stated net weight of the frozen product when sampled and weighed according to the method prescribed in National Institute of Standards and Technology (NIST) Handbook 133 Chapter 2, Section 2.6.[1]

(2) [Reserved]

[1] U.S. Department of Commerce. NIST Handbook 133: Checking the Net Contents of Packaged Goods, 2013. Washington, DC.

(f) *Nutrition labeling.* The requirements for nutrition labeling of meat and meat food products in part 317, subpart B, of this chapter, also apply to the labeling of fish and fish food products.

(g) *Label approval.* The requirements for the label approval of meat and meat food products in part 412 of this chapter, also apply to the labeling of fish and fish products.

PART 544—FOOD INGREDIENTS PERMITTED

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 544.1 Use of food ingredients.

(a) No fish product may bear or contain any food ingredient that would render it adulterated or misbranded or that is not approved in part 424 of this chapter, or in this part or elsewhere in this subchapter, or by the Administrator in specific cases.

(b) [Reserved]

[80 FR 75616, Dec. 2, 2015]

PART 548—PREPARATION OF PRODUCTS

Sec.

AUTHORITY: 7 U.S.C. 1633; 21 U.S.C. 601–602, 606–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 548.1 Preparation of fish products.

(a) All processes used in preparing any fish product in official establishments shall be subject to inspection by

Program employees unless such preparation is conducted as or consists of operations that are exempted from inspection under 9 CFR 303.1. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. To carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to ensure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter.

§ 548.2 Requirements concerning ingredients and other articles used in the preparation of fish products.

All ingredients and other articles used in the preparation of any fish product must be clean, sound, healthful, wholesome, and otherwise such as will not result in the product's being adulterated.

§ 548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

Samples of products, water, dyes, chemicals, preservatives, spices, or other articles in any official establishment shall be taken, without cost to the Program, for examination, as often as may be deemed necessary for the efficient conduct of the inspection.

§ 548.4 [Reserved]

§ 548.5 Ready-to-eat fish products.

Ready-to-eat fish products are subject to the requirements in part 430 of this chapter.

§ 548.6 Canning and canned products.

The requirements for canning and canned products in 9 CFR part 431 apply to fish products that are canned.

[80 FR 75616, Dec. 2, 2015, as amended at 83 FR 25325, May 31, 2018]

§ 548.7 Use of new animal drugs.

Edible tissues of fish with residues exceeding tolerance levels specified in 21 CFR part 556 or established in an import tolerance under 21 U.S.C. 360b(a)(6) are adulterated within the meaning of section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act because they bear or contain a new animal drug that is unsafe within the meaning of section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 548.8 Polluted water contamination at establishment

In the event that there is polluted water (including but not limited to flood water) in an official establishment, all products and ingredients for use in the preparation of the products that have been rendered adulterated by the water must be condemned. After the polluted water has receded from the establishment, the establishment must follow the cleaning and sanitizing procedures in § 318.4 of this chapter.

§ 548.9 Accreditation of non-Federal chemistry laboratories.

A non-Federal analytical laboratory that has met the requirements for accreditation specified in 9 CFR part 439 and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of regulatory samples is to be made by the establishment using the accredited laboratory.

PART 549 [RESERVED]

PART 550—RECORDS REQUIRED TO BE KEPT

Sec.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 550.1 Records required to be kept.

The requirements in 9 CFR 320.1 for records to be kept apply to persons that engage in businesses relating to fish and fish products as they do to persons that engage in businesses relating to the carcasses, parts, or products of other species amenable to the FMIA.

§ 550.2 Place of maintenance of records.

The requirements in 9 CFR 320.2 for the place where records are to be maintained apply in the keeping of records under this part.

§ 550.3 Record retention period.

The record retention requirements in 9 CFR 320.3 apply to records required to be kept under this part.

§ 550.4 Access to and inspection of records, facilities and inventory; copying and sampling.

The provisions of 9 CFR 320.4 apply to businesses dealing in fish and fish products.

§ 550.5 Registration.

The registration requirements in 9 CFR 320.5 apply to persons engaging in businesses, in or for commerce, relating to fish and fish products as they do to persons engaging in businesses relating to the carcasses, parts, and products, or any livestock, of other animal species that are amenable to the FMIA.

§ 550.6 Information and reports required from official establishment operators.

The information and reporting requirements in 9 CFR 320.6 for operators of official establishments apply with respect to fish and fish products as they do with respect to other species amenable to the FMIA.

§ 550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

The requirements in 9 CFR 320.7 for reports by consignees of allegedly adulterated or misbranded products apply with respect to fish and fish products as they do with respect to products of other species amenable to the Act.

PART 552—EXPORTS

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 552.1 Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.

(a) The manner of affixing stamps and marking products for export is that prescribed in § 322.1(a) of this chapter.

(b) The requirements for the issuance of export certificates are as prescribed in § 322.2 of this chapter.

(c) The requirements for clearing vessels and other transportation vehicles are set out in § 322.4 of this chapter.

[80 FR 75616, Dec. 2, 2015]

PART 555—TRANSPORTATION OF FISH PRODUCTS IN COMMERCE

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 555.1 Transportation of fish products.

(a) No person may sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any fish or fish product that is capable of being used as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except otherwise provided in this paragraph or in part 557 of this subchapter.

(b) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, fish products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under § 560.3 of this subchapter, any fish product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated.

(c) Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment.

(d) The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Agency's discretion and shall be adequate to determine if fish product in such conveyance is, or when moved could become, adulterated.

(e) Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that fish product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected.

Fish product placed in any means of conveyance that is found by the inspector to be in such condition that the fish product may have become adulterated shall be removed from the means of conveyance and handled in accordance with part 539 or § 540.3 of this subchapter.

§ 555.2 Fish product transported within the United States as part of export movement.

When any shipment of any fish product is offered to any carrier for transportation within the United States as a part of an export movement, the same certificate shall be required as if the shipment were destined to a point within the United States.

§ 555.3 Unmarked, inspected fish product transported under official seal between official establishments for further processing; certificate.

The requirements governing transportation of fish product that has been inspected and passed, but not so marked, from one official establishment to another official establishment are the same as those in § 325.5 of this chapter that apply to unmarked inspected meat products.

§ 555.4 Handling of fish products that may have become adulterated.

The provisions of § 325.10 of this chapter regarding the handling of products that may have become adulterated or

misbranded apply to fish and fish products.

§ 555.5 Transportation of inedible fish product in commerce.

The provisions in § 325.11(e) of this chapter regarding the transportation of inedible livestock products apply to the transportation of inedible fish parts or products.

§ 555.6 Certificates.

The provisions in § 325.14 of this chapter regarding the filing of original certificates of unmarked inspected meat products delivered to carriers applies with respect to fish and fish products.

§ 555.7 Official seals; forms, use, and breaking.

The official seals required by this part are those prescribed in § 541.3 and § 312.5 of this chapter.

§ 555.8 Loading or unloading of fish products in sealed transport conveyances.

The requirements in 9 CFR 325.17 governing the unloading of any meat or meat food product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any means of conveyance after the product leaves an official establishment are applicable to fish and fish products.

§ 555.9 Diverting of shipments

(a) Shipments of inspected and passed fish products that bear the inspection legend may be diverted from the original destination without a reinspection of the articles if the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with § 325.15 of this chapter.

(b) In case of a wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the shipment may be diverted from the original destination, without another shipper's certificate; but in all such cases the carrier must immediately report the facts by telephone or telegraph to the District Manager in the area in which the emergency occurs. The report must include the following information:

(1) Nature of the emergency.

(2) Place where seals were broken.

(3) Original points of shipment and destination.

(4) Number and initial of the original car or truck.

(5) Number and initials of the car or truck into which the articles are reloaded.

(6) New destination of the shipment.

(7) Kind and amount of articles.

§ 555.10 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this part do not apply:

(a) To specimens of product sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To material released for educational, research, and other nonfood purposes, as prescribed in § 540.2 of this subchapter;

(c) To tissues for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in § 540.2 of this subchapter;

(d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and

(e) To articles that are naturally inedible by humans.

§ 555.11 Transportation and other transactions concerning dead, dying, or diseased fish, and fish or parts of fish that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless the fish and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 550 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by FSIS as one that imposes requirements at least equal to the Federal requirements for purposes of section 301(c) of the Act;

(b) Buy in commerce or import any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 550 of this subchapter, or is the operator of an establishment inspected as required by paragraph (a) of this section and such fish or parts of fish are to be delivered to establishments eligible to receive them under paragraph (a) of this section;

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided*, That any such dead, dying, or diseased fish, or parts of fish may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier must immediately report the facts by telephone or other electrical or electronic means to the Office of Investigation, Enforcement and Audit, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) Load into any means of conveyance containing any dead, dying, or diseased fish, or parts of fish that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any fish or parts of fish not within the foregoing description or any other products or other commodities.

§ 555.12 Means of conveyance in which dead, dying, or diseased fish or parts of fish must be transported.

All vehicles and other means of conveyance used by persons subject to § 555.11 for transporting in commerce or importing, any dead, dying, or diseased fish or parts of fish that died otherwise by slaughter must be leak proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance used in conveying the fish or parts of fish must be cleaned and disinfected before being used in the transportation of any product intended for use as human food. The cleaning procedure must include the complete removal from the means of conveyance of any fluid, parts, or product of dead, dying, or diseased fish and the thorough application of a disinfectant approved by the Administrator to the interior surfaces of the cargo space.

PART 557—IMPORTATION

Sec.

AUTHORITY: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 557.1 Definitions; application of provisions.

(a) When used in this part, the following terms shall be construed to mean:

(1) *Import.* To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer for entry.* Presentation of the imported product by the importer to the Program for reinspection.

(3) *Entry.* The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with § 557.26 of this subchapter.

(b) The provisions of this part shall apply to fish and fish products that are capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance with applicable requirements under other laws, including the provisions in part 94 of chapter I of this title.

§ 557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.

(a) The requirements in 9 CFR 327.2(a)(1), (a)(2)(i), (a)(2)(ii)(C)–(I), (a)(2)(iii)–(iv), and (a)(3), for determining the acceptability of foreign meat inspection systems for the importation of meat and meat food products into the United States, apply in determining the acceptability of foreign fish inspection systems for the importation of fish and fish products into the United States. In determining the acceptability of these systems, the Agency will evaluate the manner in which they take into account the conditions under which fish are raised and transported to a processing establishment.

(b)(1) It has been determined that fish and fish products from the following countries covered by foreign inspection certificates of the country of origin as required by § 557.4, are eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part: (None listed as of December 2, 2015).

(2) Persons interested in having the most recent list of eligible countries and establishments may contact the Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

§ 557.3 No fish or fish product to be imported without compliance with applicable regulations.

No fish or fish product offered for importation from any foreign country shall be admitted into the United States if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product.

§ 557.4 Imported fish and fish products; foreign certificates required.

(a) Except as provided in § 557.16, each consignment containing any fish or fish products consigned to the United States from a foreign country must be accompanied by an electronic foreign inspection certificate or a paper foreign inspection certificate for fish and

fish products. The certificate must have been issued by an official of the foreign government agency responsible for the inspection and certification.

(b) An official of the foreign government must certify that any fish or fish product described on any official certificate was produced in accordance with the regulatory requirements in § 557.2.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification;

(8) The net weight of each lot;

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

§ 557.5 Importer to make application for inspection of fish and fish products for entry.

(a) Applicants must submit an import inspection application, to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted, electronically or on paper, to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 557.16 and 557.17.

§ 557.6 Fish and fish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

(a)(1) Except as provided in §§ 557.16 and 557.17, all fish and fish products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.

(3) The electronic inspection system will be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic system.

(b) Fish and fish products required by this part to be inspected must be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section.

(c) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application must be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, and must include all information called for by that form.

(d) Approval for Federal import inspection must be in accordance with §§ 304.1 and 304.2 of this chapter. Also, before approval is granted, the establishment must have developed written Sanitation Standard Operating Procedures in accordance with part 416 of this chapter.

(e) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 307.1, 307.2(b), (d), (f), (h), (k), and (l) and 416.1 through 416.6 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment, provided that an application has been filed in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

(i) A product examination must be made, as provided in paragraph (a) of this section, of a foreign fish or fish product, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled fresh or frozen fresh fish shall be the same as those used for domestic fish or fish products. Samples may be collected at no cost to FSIS and submitted to an FSIS laboratory for analysis (See § 557.18).

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports

shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product to Program personnel at points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with §318.309(d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(c), (d)(1)(v), (d)(1)(vii) and (d)(1)(viii) of this chapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with §318.309(d)(1)(i) of this chapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this section may be obtained, upon request, from the Office of Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

§ 557.7 Products for importation; movement prior to inspection; handling; bond; assistance.

The requirements in 9 CFR 327.7 respecting the movement or conveyance from any port, or delivery to the consignee, of any product required to be inspected under part 327, apply to fish and fish products.

§ 557.8 Import fish and fish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.

Compartments of ocean vessels, railroad cars, and other means of conveyance transporting any fish or fish product to the United States, and all trucks, chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any fish or fish product offered for importation into the United States, shall be maintained in a sanitary condition.

§ 557.9 [Reserved]

§ 557.10 Samples; inspection of consignments; refusal of entry; marking.

The provisions in 9 CFR 327.10 governing the taking of samples, the inspection of consignments, the refusal of entry, and the controlled pre-stamping of shipments of meat and meat food products apply with respect to fish and fish products.

§ 557.11 Receipts to importers for import fish product samples.

FSIS will issue to importers official receipts for samples of foreign products collected for laboratory analysis, as provided in §327.11 of this chapter.

§ 557.12 Foreign canned or packaged fish and fish products bearing trade labels; sampling and inspection.

Foreign canned or packaged fish and fish products bearing on their immediate containers trade labels that have or have not been approved in accordance with the regulations in §541.7 of this subchapter are to be sampled and inspected in the same manner as provided by §327.12 of this chapter for foreign canned meat food products.

§ 557.13 Foreign fish and fish products offered for importation; reporting of findings to Customs.

Program inspectors are to report their findings as to any fish or fish products that have been inspected in accordance with this part in the same manner as that provided by §327.13 of this chapter for meat products. Fish and fish products that are refused entry are to be handled in the same manner as provided by §327.13 of this chapter for meat products that are refused entry. Import personnel will identify to the Port Director of U.S. Customs and Border Protection and the Importer of record any products refused entry into the United States.

§ 557.14 Marking of fish and fish products and labeling of immediate containers thereof for importation.

The regulations in 9 CFR 327.14 governing the marking of meat and meat food products and the labeling of immediate containers of those products for importation apply with respect to fish and fish products.

§ 557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

The requirements in 9 CFR 327.15 governing the marking and labeling of outside containers of meat and meat

food products apply also with respect to fish and fish products.

§ 557.16 Small importations for importer's own consumption; requirements.

The exemption in 9 CFR 327.16 for small importations of meat or meat food products for the importer's own consumption applies with respect to fish or fish products.

§ 557.17 Returned U.S. inspected and marked fish and fish products.

U.S. inspected and passed and so marked fish products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification of and approval by the Assistant Administrator, Office of Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, in specific cases.

§ 557.18 Fish or fish products offered for entry and entered to be handled and transported as domestic; exception.

The regulations in 9 CFR 327.18 governing the offer for entry into the United States of meat and meat food products apply with respect to fish and fish products. Products that fail to meet these regulatory requirements are subject to penalties as administered by the U.S. Port Director of Customs and Border Protection. Likewise, the products may be subject to detention and to being proceeded against as determined by the Administrator.

§ 557.19 Specimens for laboratory examination and similar purposes.

Importation of fish or fish product samples for trade show exhibition, laboratory examination, research, evaluative testing, trade show exhibition, or other scientific purposes are subject to the same conditions as imported meat or meat product specimens under § 327.19 of this chapter.

§ 557.20–557.23 [Reserved]

§ 557.24 Appeals; how made.

An appeal from a decision of any Program employee is to be made as provided by 9 CFR 327.24.

§ 557.25 Disposition procedures for fish and fish products condemned or ordered destroyed under import inspection.

Disposition procedures for condemned fish or fish products ordered destroyed under import inspection are as those for carcasses, parts, meat, and meat food products under 9 CFR 327.25.

§ 557.26 Official import inspection marks and devices.

The official inspection legend and other marks to be applied to imported fish and fish products are as required by 9 CFR 327.26 for meat food products prepared from cattle, sheep, swine, and goats.

PART 559—DETENTION, SEIZURE, CONDEMNATION

Sec.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 559.1 Fish and other articles subject to administrative detention.

The provisions of 9 CFR 329.1 through 329.5 governing the administrative detention of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§ 559.2 Articles or fish subject to judicial seizure and condemnation.

The provisions of 9 CFR 329.6 through 329.8 governing the judicial seizure and condemnation of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§ 559.3 Criminal offenses.

The criminal provisions of the Act apply with respect to the inspection of fish and fish products as they do with respect to the inspection of other food products subject to the Act.

PART 560—STATE-FEDERAL, FEDERAL-STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS

Sec.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 560.1 Cooperation with States and Territories.

The provisions in § 321.1 of this chapter authorizing the Administrator to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering a meat inspection program for the State or Territory apply with respect to fish and fish products inspection.

§ 560.2 Cooperation of States in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of any State in carrying out Federal functions under the FMIA, including functions relating to the inspection of fish and fish products. A cooperative program for this purpose is called a Federal-State program.

§ 560.3 Cooperation of States for the Interstate Shipment of Fish and Fish Products.

The provisions in § 321.3 authorizing the Administrator to coordinate with States that have meat inspection programs as provided in § 321.1 of this chapter to select certain establishments operating under these programs to participate in a cooperative program to ship products in interstate commerce apply with respect to fish and fish products inspection.

§ 560.4 Designation of States under the Federal Meat Inspection Act.

The requirements in part 331 of this chapter apply with respect to fish and fish products inspection, including:

(a) The requirements in 9 CFR 331.3 governing the designation of States for Federal inspection under section 301(c) of the Act (21 U.S.C. 661(c));

(b) The requirements in 9 CFR 331.5 governing the designation under section 301(c) of the Act of establishments whose operations would clearly endanger the public health; and

(c) The requirements in 9 CFR 331.6 governing the designation of States under section 205 of the Act.

PART 561—RULES OF PRACTICE

Sec.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

§ 561.1 Rules of practice governing inspection actions.

The rules of practice in part 500 of this chapter, governing inspection actions taken by FSIS with respect to establishments and products, apply to actions taken with respect to fish slaughter, fish processing, fish, and fish products regulated under this subchapter.

§ 561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.

The procedures that the Agency must follow before reporting a violation of the Federal Meat Inspection Act for prosecution by the Department of Justice are given in part 335 of this chapter.

SUBCHAPTERS G–H [RESERVED]

SUBCHAPTER I—EGG PRODUCTS INSPECTION

PART 590—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

DEFINITIONS

ADMINISTRATION

SCOPE OF INSPECTION

RELATION TO OTHER AUTHORITIES

EGGS AND EGG PRODUCTS NOT INTENDED FOR HUMAN FOOD

REFRIGERATION OF SHELL EGGS

EXEMPTIONS

PERFORMANCE OF SERVICE

APPLICATION FOR SERVICE

INAUGURATION OF SERVICE

DENIAL OF SERVICE

RECORDS AND RELATED REQUIREMENTS FOR EGGS AND EGG PRODUCTS HANDLERS AND RELATED INDUSTRIES

ADMINISTRATIVE DETENTION

APPEAL OF AN INSPECTION OR DECISION

CERTIFICATES

IDENTIFYING AND MARKING PRODUCT

AUTHORITY: 21 U.S.C. 1031–1056.

SOURCE: 36 FR 9814, May 28, 1971, unless otherwise noted. Redesignated at 42 FR 32514, June 27, 1977 and 46 FR 63203, Dec. 31, 1981. Further redesignated at 63 FR 72353, Dec. 31, 1998.

DEFINITIONS

§ 590.1 Meaning of words.

Under these regulations, words in the singular shall be deemed to mean the plural and vice versa, as the case may demand.

§ 590.5 Terms defined.

For the purpose of these regulations, unless the context otherwise requires, the following terms shall be construed, respectively, as follows:

Acceptable means suitable for the purpose intended and acceptable to the Administrator.

Act means the applicable provisions of the Egg Products Inspection Act (Pub. L. 91–597, 84 Stat. 1620 *et seq.*).

Administrator means the Administrator of the Agricultural Marketing Service of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

Adulterated means any egg or egg product under one or more of the following circumstances:

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(b)(1) If it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may in the judgment of the Secretary, make such article unfit for human food;

(2) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(3) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(4) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: Provided, that an article which is not otherwise deemed adulterated under paragraph (b)(2), (3), or (4) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive, in or on such article, is prohibited by regulations of the Secretary in official plants;

(c) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human food;

(d) If it has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(e) If it is an egg which has been subjected to incubation or the product of any egg which has been subjected to incubation;

(f) If its container is composed, in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health;

(g) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act; or

(h) If any valuable constituent has been, in whole or in part, omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Ambient temperature means the air temperature maintained in an egg storage facility or transport vehicle.

Applicant means any person who requests any inspection service as authorized under the Act or the regulations of this part.

Capable of use as human food means any egg or egg product, unless it is denatured, or otherwise identified, as required by these regulations to deter its use as human food.

Chief of the Grading Branch means Chief of the Poultry Grading Branch, Poultry Division, Agricultural Marketing Service.

Class means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind, type, or method of processing.

Commerce means interstate, foreign, or intrastate commerce.

Condition means any condition (including, but not being limited to, the state of preservation, cleanliness, soundness, wholesomeness, or fitness for human food) of any product which affects its merchantability; or any condition, including but not being limited to, the processing, handling, or packaging which affects such product.

Container or *Package* includes for egg products, any box, can, tin, plastic, or other receptacle, wrapper, or cover and for shell eggs, any carton, basket, case, cart, pallet, or other receptacle.

(a) *Immediate container* means any package or other container in which egg products or shell eggs are packed for household or other ultimate consumers.

(b) *Shipping container* means any container used in packing an immediate container.

Department means the U.S. Department of Agriculture.

Dirty egg or *Dirties* means an egg(s) that has an unbroken shell with adhering dirt or foreign material.

Egg means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea. Some of the terms applicable to shell eggs are as follows:

(a) *Check* means an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(b) *Clean and sound shell egg* means any egg whose shell is free of adhering dirt or foreign material and is not cracked or broken.

(c) *Dirty egg* or *Dirties* means an egg(s) that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.

(d) *Incubator reject* means an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(e) *Inedible* means eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(f) *Leaker* means an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(g) *Loss* means an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

(h) *Restricted egg* means any check, dirty egg, incubator reject, inedible, leaker, or loss.

Egg handler means any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs (as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food.

Egg product means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products. For the purposes of this part, the following

products, among others, are exempted as not being egg products: Freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, and sandwiches containing eggs or egg products, provided, such products are prepared from inspected egg products or eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. Balut and other similar ethnic delicacies are also exempted from inspection under this part.

Eggs of current production means shell eggs which have moved through the usual marketing channels since the time they were laid and are not in excess of 60 days old.

Fair Packaging and Labeling Act means the Act so entitled, approved November 3, 1966 (80 Stat. 1296), and Acts amendatory thereof or supplementary thereto.

Federal Food, Drug, and Cosmetic Act means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Inspection means the application of such inspection methods and techniques as are deemed necessary by the responsible Secretary to carry out the provisions of the Egg Products Inspection Act and the regulations under this part.

Inspection service means the official service within the Department having the responsibility for carrying out the provisions of the Egg Products Inspection Act. Inspection service also means the activities performed, including official reporting by such official service.

Inspector/Grader means:

(a) Any employee or official of the United States Government authorized to inspect eggs or egg products under the authority of this part; or

(b) Any employee or official of the government of any State or local jurisdiction authorized by the Secretary to inspect eggs or egg products under the authority of this part, under an agreement entered into between the Secretary and the appropriate State or other agency.

Interested party means any person financially interested in a transaction involving any inspection or appeal inspection of any product, or the decision of an inspector.

Label means a display of any printed, graphic, or other method of identification upon the shipping container, if any, or upon the immediate container, including but not limited to, an individual consumer package of eggs and egg products, or accompanying such product.

Misbranded means any egg products which are not labeled and packaged in accordance with the requirements prescribed by regulations of the Administrator under this part.

National Supervisor means:

(a) The officer in charge of the inspection service; and

(b) Such other employee of the Service as may be designated by him.

Nest-run eggs means eggs which are packed as they come from the production facilities without having been washed, sized and/or candled for quality, with the exception that some checks, dirties, or other obvious undergrades may have been removed.

Official certificate means any certificate prescribed by regulations of the Administrator for issuance by an inspector or other person performing official functions under this part.

Official device means any device prescribed or authorized by the Secretary for use in applying any official mark.

Official identification means the official inspection mark or any other symbol prescribed by regulations of this part to identify the status of any article.

Official inspection mark means any symbol prescribed by the regulations of the Administrator showing that egg products were inspected in accordance with this part.

Official standard means the standards of quality, grades, and weight classes for eggs.

Office of inspection means the office of any inspector.

Pasteurize means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable microorganisms by such processes as may be prescribed by these regulations.

Person means any individual, partnership, corporation, association, or other business unit.

Pesticide chemical, *Food additive*, *Color additive*, and *Raw agricultural commodity* shall have the same meaning for purposes of this part as under the Federal Food, Drug, and Cosmetic Act.

Plant means any place of business where egg products are processed:

(a) *Exempted plant* means any plant where the Administrator has determined the facilities and operating procedures meet such standards as may be prescribed by this part, and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards of U.S. Consumer Grade B for shell eggs, and where an exemption has been granted.

(b) *Official plant* means any plant in which the plant facilities, methods of operation and sanitary procedures have been found suitable and adequate by the Administrator for the continuous inspection of egg products in accordance with this part and in which inspection service is carried on.

Potable water means water that has been approved by a State health authority or other agency or laboratory acceptable to the Administrator as safe for drinking and suitable for food processing.

Processing means manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging egg products at official plants.

Producer-packer means any producer who sorts eggs only from his own production and packs them into their various qualities.

Quality means the inherent properties of any product which determine its relative degree of excellence.

Regional Director means any employee of the Department in charge of inspection service in a designated geographical region.

Regulations means the provisions in this part.

Regulatory inspector means any employee of the U.S. Government, or State or local jurisdiction, who is authorized by the Secretary to make such inspections as required in § 590.28 of these regulations.

Sampling means the act of taking samples of any product for inspection or analyses.

Sanitize means the application of a bactericidal treatment which is approved as being effective in destroying microorganisms, including pathogens.

Secretary means the Secretary of Agriculture or his delegate.

Service means the Agricultural Marketing Service (AMS) of the Department.

Shell egg packer (grading station) means any person engaged in the sorting of eggs from sources other than or in addition to his own production into their various qualities, either mechanically or by other means.

Stabilization means the subjection of any egg product to a desugaring process.

State means any State of the United States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and the District of Columbia.

Ultimate consumer means any household consumer, restaurant, institution, or any other party who has purchased or received shell eggs or egg products for consumption.

United States means the States.

Washed ungraded eggs means eggs which have been washed but not sized or segregated for quality.

White or albumen means, for the purpose of this part, the product obtained from the egg as broken from the shell and separated from the yolk.

[36 FR 9814, May 28, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 590.5, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

ADMINISTRATION

§ 590.10 Authority.

The Administrator shall perform, for and under the supervision of the Secretary, such duties as the Secretary may require in the enforcement or administration of the provisions of the Act, and this part. The Administrator may waive for a limited period any particular provisions of the regulations to permit experimentation so that new

procedures, equipment, and processing techniques may be tested to facilitate definite improvements and at the same time to maintain full compliance with the spirit and intent of the regulations. The Agricultural Marketing Service and its officers and employees shall not be liable in damages through acts of commission or omission in the administration of this part.

[42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.13 Federal and State cooperation.

The Secretary shall, whenever he determines that it would effectuate the purposes of the Act, authorize the Administrator to cooperate with appropriate State and other governmental agencies in carrying out any provisions of the Egg Products Inspection Act and these regulations. In carrying out the provisions of the Act and the regulations, the Secretary may conduct such examinations, investigations, and inspections as he determines practicable through any officer or employee of any such agency commissioned by him for such purpose. The Secretary shall reimburse the States and other agencies for the services rendered by them in such cooperative programs as agreed to in the cooperative agreements as signed by the Administrator and the duly authorized agent of the State or other agency.

§ 590.17 Nondiscrimination.

The conduct of all services and the licensing of graders and inspectors under these regulations shall be accomplished without discrimination as to race, color, religion, sex, national origin, age, or disability.

[40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977. Further redesignated at 46 FR 63203, Dec. 31, 1981, and amended at 60 FR 49169, Sept. 21, 1995]

§ 590.18 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

(a) *Purpose.* This section collects and displays the control numbers assigned to information collection requirements by the Office of Management and Budget contained in 7 CFR 590 pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511.

(b) *Display.*

7 CFR section where identified and described	Current OMB control number
§ 590.10	0581–0113
§ 590.13	0581–0113
§ 590.22	0581–0113
§ 590.28(a)(1)	0581–0113
§ 590.40	0581–0113
§ 590.45(c)(1)	0581–0113
§ 590.45(c)(3)	0581–0113
§ 590.45(d)	0581–0113
§ 590.110(a)	0581–0113
§ 590.112	0581–0113
§ 590.122	0581–0113
§ 590.124	0581–0113
§ 590.126	0581–0113
§ 590.128(a)	0581–0113
§ 590.140	0581–0113
§ 590.144	0581–0113
§ 590.146(b)	0581–0113
§ 590.146(d)	0581–0113
§ 590.155	0581–0113
§ 590.160(c)	0581–0113
§ 590.160(d)	0581–0113
§ 590.160(f)(3)	0581–0113
§ 590.160(f)(4)	0581–0113
§ 590.200(a)	0581–0113
§ 590.200(b)	0581–0113
§ 590.220	0581–0113
§ 590.240	0581–0113
§ 590.320	0581–0113
§ 590.402(a)	0581–0113
§ 590.411(a)	0581–0113
§ 590.411(b)	0581–0113
§ 590.411(e)	0581–0113
§ 590.411(f)	0581–0113
§ 590.418(c)	0581–0113
§ 590.430(b)	0581–0113
§ 590.435(b)	0581–0113
§ 590.435(c)	0581–0113
§ 590.440(c)	0581–0113
§ 590.500(h)	0581–0113
§ 590.504(c)	0581–0113
§ 590.504(d)	0581–0113
§ 590.504(h)	0581–0113
§ 590.504(k)	0581–0113
§ 590.504(o)(1)	0581–0113
§ 590.504(o)(2)	0581–0113
§ 590.504(o)(3)(i)	0581–0113
§ 590.504(o)(3)(iii)	0581–0113
§ 590.504(o)(3)(iv)	0581–0113
§ 590.504(o)(3)(v)	0581–0113
§ 590.515(a)(8)	0581–0113
§ 590.520(h)	0581–0113
§ 590.522(f)	0581–0113
§ 590.522(x)	0581–0113
§ 590.522(aa)(2)	0581–0113
§ 590.530(d)	0581–0113
§ 590.534(a)	0581–0113
§ 590.544(b)	0581–0113
§ 590.544(c)	0581–0113
§ 590.544(d)	0581–0113
§ 590.552(a)(3)	0581–0113
§ 590.552(b)(1)(i)	0581–0113
§ 590.552(b)(2)	0581–0113
§ 590.570(c)	0581–0113
§ 590.575(b)(3)	0581–0113
§ 590.575(d)	0581–0113
§ 590.580(c)	0581–0113
§ 590.600	0581–0113
§ 590.610(a)	0581–0113
§ 590.620	0581–0113

7 CFR section where identified and described	Current OMB control number
§ 590.640(b)(1)	0581–0113
§ 590.680(a)	0581–0113
§ 590.800	0581–0113
§ 590.840	0581–0113
§ 590.905(a)	0581–0113
§ 590.915(a)	0581–0113
§ 590.915(b)	0581–0113
§ 590.920	0581–0113
§ 590.930(f)	0581–0113
§ 590.950(a)	0581–0113
§ 590.960	0581–0113
§ 590.965	0581–0113

[48 FR 34238, July 28, 1983, as amended at 50 FR 23270, June 3, 1985; 54 FR 37290, Sept. 8, 1989]

SCOPE OF INSPECTION

§ 590.20 Inspection in accordance with methods prescribed or approved.

Inspection of eggs and egg products shall be rendered pursuant to these regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

§ 590.22 Basis of service.

These regulations provide for inspection services pursuant to the Egg Products Inspection Act. Eggs and egg products shall be inspected in accordance with such standards, methods, and instructions as may be issued or approved by the Administrator. Inspection services shall be subject to supervision at all times by the applicable Federal-State supervisor, egg products supervisor, Regional Director, and National Supervisor.

§ 590.24 Egg products plants requiring continuous inspection.

No plant in which egg products processing operations are conducted shall process egg products without continuous inspection under these regulations, except as expressly exempted in § 590.100.

§ 590.26 Egg products entering or prepared in official plants.

Eggs and egg products processed in an official plant shall be inspected, processed, marked, and labeled as required by these regulations. Egg products entering an official plant shall have been inspected, processed, marked, and labeled as required by these regulations.

§ 590.28 Other inspections.

(a) Periodic inspections shall be made of:

(1) The records of all persons engaged in the business of transporting, shipping, or receiving any eggs or egg products.

(2) Exempted plants to determine that such plants are operating pursuant to these regulations.

(b) Inspections shall be made of imported eggs and egg products as required in this part.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, and amended at 60 FR 49169, Sept. 21, 1995; 63 FR 45675, Aug. 27, 1998; 63 FR 69971, Dec. 17, 1998]

RELATION TO OTHER AUTHORITIES

§ 590.30 At official plants.

(a) Requirements within the scope of the Act with respect to premises, facilities, and operations of any official plant which are in addition to or different than those made under this part may not be imposed by any State or local jurisdiction except that any such jurisdiction may impose recordkeeping and other requirements within the scope of § 590.200, if consistent therewith, with respect to any such plant.

(b) Labeling, packaging, or ingredient requirements in addition to or different than those made under this part, the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act may not be imposed by any State or local jurisdiction with respect to egg products processed at any official plant in accordance with the requirements under this part and such Acts.

§ 590.35 Eggs and egg products outside official plants.

Any State or local jurisdiction may exercise jurisdiction with respect to eggs and egg products for the purpose of preventing the distribution for human food purposes of any such articles which are outside of the official plant and are in violation of this part or any of said Federal Acts or any

State or local law consistent therewith.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69971, Dec. 17, 1998]

EGGS AND EGG PRODUCTS NOT INTENDED FOR HUMAN FOOD

§ 590.40 Continuous inspection not provided.

Continuous inspection shall not be provided under this part at any plant for the processing of any egg products which are not intended for use as human food, but such articles prior to their offer for sale or transportation in commerce shall be denatured or decharacterized unless shipped under seal as authorized in §§ 590.504(c), and identified as prescribed by the regulations in this part to prevent their use for human food. Periodic inspections shall be made of such operations and records to assure compliance with the Act and the regulations in this part.

[37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69971, Dec. 17, 1998]

§ 590.45 Prohibition on eggs and egg products not intended for use as human food.

(a) No person shall buy, sell, or transport or offer to buy or sell, or offer or receive for transportation in commerce, any eggs or egg products which are not intended for use as human food, unless they are denatured or decharacterized, unless shipped under seal as authorized in paragraphs (c) and (d) of this section or in §§ 590.504(c) and 590.720(a) and identified as required by the regulations in this part.

(b) No person shall import or export shell eggs classified as loss, inedible, or incubator rejects or any egg products which are unwholesome, adulterated, or are otherwise unfit for human food purposes, except as provided in paragraphs (c) and (d) of this section, unless they are denatured or decharacterized and identified as required by the regulations in this part.

(c) Egg products which are unwholesome, adulterated, or are otherwise unfit for human food purposes that are not denatured or decharacterized may be exported to foreign countries for industrial use or animal food under the following provisions:

(1) Authorized government official of the foreign country shall approve the importation of such products into that country.

(2) The egg products shall be shipped under U.S. Government seal and identified as required in § 590.840.

(3) Provisions for the control of such inedible product in the foreign country to preclude its use as human food must be established and approved by the Administrator. Such control may consist of, but not be limited to, receipt and inspection by an appropriate U.S. Government official, an official of an approved meat, poultry, or egg products inspection system of the foreign government, or, when acceptable to the Administrator, a foreign government official including other foreign health authorities.

(d) Foreign governments may petition the Administrator for approval to import into this country egg products which are unwholesome, adulterated, or otherwise unfit for human food purposes that are not denatured or decharacterized for industrial use or animal food requirements. Such products shall be subject to the provisions of this part and other applicable laws and regulations for importation into the United States.

[48 FR 34238, July 28, 1983]

REFRIGERATION OF SHELL EGGS

§ 590.50 Temperature and labeling requirements.

(a) No shell egg handler shall possess any shell eggs that are packed into containers destined for the ultimate consumer unless they are stored and transported under refrigeration at an ambient temperature of no greater than 45 °F (7.2 °C).

(b) No shell egg handler shall possess any shell eggs that are packed into containers destined for the ultimate consumer unless they are labeled to indicate that refrigeration is required.

(c) Any producer-packer with an annual egg production from a flock of 3,000 or fewer hens is exempt from the

temperature and labeling requirements of this section.

[63 FR 45675, Aug. 27, 1998]

EXEMPTIONS

§ 590.100 Specific exemptions.

The following are exempt to the extent prescribed as to the provision for continuous inspection of processing operations in section 5(a) of the Act: *Provided*, That the conditions for exemption and provisions of these regulations are met:

(a) [Reserved]

(b) Subject to the approval of the Administrator as provided in §§ 590.600 through 590.670, the processing of egg products without continuous inspection at any plant where the facilities, sanitation, and operating procedures are the same as are required in this part for official plants and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards for U.S. Consumer Grade B shell eggs, and the egg products processed at such plant;

(c)–(d) [Reserved]

(e) The processing and sale of egg products by any poultry producer from eggs of his own flock's production when sold directly to a household consumer exclusively for use by such consumer and members of his household and his nonpaying guests and employees;

(f) [Reserved]

(g) The processing in nonofficial plants, including but not limited to bakeries, restaurants, and other food processors, without continuous inspection, of certain categories of food products which contain eggs or egg products as an ingredient, and the sale and possession of such products: *Provided*, That such products are manufactured from inspected egg products processed in accordance with this part or from eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs;

[36 FR 9814, May 28, 1971, as amended at 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69971, Dec. 17, 1998]

§ 590.105 Suspension or termination of exemptions.

(a) The Administrator may immediately suspend or terminate any exemption under § 590.100(b) at any time with respect to any person, if the conditions of exemption prescribed by this section are not being met. The Administrator may modify or revoke any regulation of this part, granting exemptions whenever he determines such action appropriate to effectuate the purposes of the Act.

(b) Failure to comply with the condition of the exemptions contained in § 590.100 shall subject such person to the penalties provided for in the Act and in this part.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

PERFORMANCE OF SERVICE

§ 590.110 Licensed inspectors.

(a) Any person who is a Federal or State employee, or the employee of a local jurisdiction possessing proper qualifications as determined by an examination for competency and who is to perform services pursuant to this part, may be licensed by the Secretary as an inspector.

(b) Licenses issued by the Secretary are to be countersigned by the Administrator or by any other designated official of the Service.

(c) No person may be licensed to inspect any product in which he is financially interested.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.112 Suspension of license or authority; revocation.

Pending final action by the Secretary, any person authorized to countersign a license to perform inspection services may, whenever he deems such action necessary to assure that any inspection service is properly performed, suspend any license to perform inspection services issued pursuant to this part by giving notice of such suspension to the respective licensee, accompanied by a statement of the reasons

therefor. Within 7 days after the receipt of the aforesaid notice and statement of reasons by the licensee, he may file an appeal in writing, with the Secretary, supported by any argument or evidence that he may wish to offer as to why his license should not be suspended or revoked. After the expiration of the aforesaid 7-day period and consideration of such argument and evidence, the Secretary will take such action as he deems appropriate with respect to such suspension or revocation. When no appeal is filed within the prescribed 7 days, the license is revoked or suspended.

§ 590.114 Surrender of license.

Upon termination of his services as an inspector or whenever his license has been suspended or revoked, the licensee shall surrender his license and other items of identification furnished by the Department immediately to the inspection service.

§ 590.116 Activities of inspectors.

Inspectors at official plants shall confine their activities to those duties necessary in the rendering of inspection service and such closely related activities as may be approved by the Administrator.

§ 590.118 Identification.

Inspectors shall have in their possession at all times while on duty, and present upon request, the means of identification furnished by the Department to such persons.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.119 Political activity.

Inspectors are forbidden during the period of their respective appointments, or licenses, to take an active part in political management or in political campaigns. Political activity in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, except as authorized by law or regulation of the Department, is prohibited. This applies to all appointees, including but not being limited to temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of this section or § 590.120 will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

[36 FR 9814, May 28, 1971, as amended at 42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.120 Financial interest of inspectors.

No inspector shall inspect any product in which he is financially interested.

§ 590.122 Time of inspection.

The inspector who is to perform the inspection in an official plant shall be given reasonable advance notice by plant management of the hours when such inspection will be required.

[60 FR 49169, Sept. 21, 1995]

§ 590.124 Schedule of operation of official plants.

Operating schedules for an official plant shall be subject to approval of the Administrator. The normal operating schedule shall consist of a continuous 8-hour period per day and shall include the time for FSIS inspection program personnel to put on required gear and to walk to a work station, and the time for FSIS inspection program personnel to return from a work station and remove required gear (excluding not to exceed 1 hour for lunch), 5 consecutive days per week, within the administrative workweek, Sunday through Saturday, for each full shift required. Clock hours of daily operations need not be specified in a schedule, although as a condition of continuance of approval of a schedule, the hours of operation must be reasonably uniform from day to day.

[48 FR 20683, May 9, 1983, as amended at 76 FR 33980, June 10, 2011]

§ 590.126 Overtime inspection service.

When operations in an official plant require the services of inspection personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime

work. The official plant must give reasonable advance notice to the inspector of any overtime service necessary and must pay for such overtime. For each calendar year, FSIS will calculate the overtime rate for inspection service, per hour per program employee, using the following formula: The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, multiplied by 1.5, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate. FSIS calculates the benefits rate, the travel and operating rate, the overhead rate, and the allowance for bad debt rate using the formulas set forth in § 592.510(b) and the cost of living increases and percentage of inflation factors set forth in § 592.510(c) of this chapter.

[71 FR 2143, Jan. 13, 2006, as amended at 76 FR 20228, Apr. 12, 2011]

§ 590.128 Holiday inspection service.

(a) When an official plant requires inspection service on a holiday or a day designated in lieu of a holiday, such service is considered holiday work. The official plant must, in advance of such holiday work, request the inspector in charge to furnish inspection service during such period and must pay the Agency for such holiday work at the hourly rate. For each calendar year, FSIS calculates the holiday rate for inspection service, per hour per program employee, using the following formula: The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, multiplied by 2, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate. FSIS will calculate the benefits rate, the travel and operating rate, the overhead rate, and the allowance for bad debt rate using the formulas set forth in § 592.510(b), and the cost of living increases and percentage of inflation factors set forth in § 592.510(c) of this chapter.

(b) The term ''holiday'' shall mean the legal public holidays specified by the Congress in paragraph (a) of section 6103, title 5 of the United States Code. Information on legal holidays may be obtained from the supervisor.

[37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, as amended at 46 FR 9, Jan. 2, 1981. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46071, Oct. 15, 1982; 59 FR 52637, Oct. 18, 1994; 65 FR 60095, Oct. 10, 2000; 67 FR 3430, Jan. 24, 2002; 68 FR 37957, June 26, 2003; 71 FR 2143, Jan. 13, 2006; 76 FR 20228, Apr. 12, 2011]

§ 590.130 Basis of billing plants.

Overtime and/or holiday services shall be billed to the official plant on the basis of each 15 minutes of overtime and/or holiday service performed by each inspector providing such service to the plant, except that when an official plant requires the services of an inspector after he has completed his day's assignment and left the plant or when he is called back to duty on a day outside the established normal operating schedule or on a holiday, the official plant shall pay for a minimum of 2 hours service at the applicable established rate. Extra travel expense incurred while rendering overtime or holiday service shall be billed to the official plant. Bills are payable upon receipt and become delinquent 30 days from date of billing. Overtime or holiday inspection service will not be performed at any plant that is delinquent, and processing operations shall be confined to the regular operating schedule of the plant. In addition, fees will be charged and collected for certifications requested by and provided for the official plant that are not within the scope of these regulations.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995; 65 FR 44950, July 20, 2000]

§ 590.132 Access to plants.

Access shall not be refused to any representative of the Secretary to any plant, place of business, or transport

vehicle subject to inspection under the provisions of this part upon presentation of proper credentials.

[63 FR 45675, Aug. 27, 1998]

§ 590.134 Accessibility of product and cooler rooms.

(a) Each product for which inspection service is required shall be so placed as to disclose fully its class, quality, quantity, and condition as the circumstances may warrant.

(b) The perimeter of each cooler room used to store shell eggs packed in containers destined for the ultimate consumer shall be made accessible in order for the Secretary's representatives to determine the ambient temperature under which shell eggs are stored.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 45675, Aug. 27, 1998]

§ 590.136 Facilities and equipment to be furnished by official plants for use of inspectors in performing service.

(a) Such facilities and equipment shall include but not be limited to a room or area suitable for sampling product, and acceptable candling light, flashlight, heavy duty, high speed drill with an eleven sixteenths-inch or larger bit of sufficient length to reach the bottom of containers used for frozen eggs, metal stem thermometer(s), test thermometer(s), stop watch, test weighing scale(s) and test weight(s), test kit for determining the bactericidal strength of sanitizing solutions, and stationary or adequately secured storage box or cage (capable of being locked only by the inspector) for holding official samples.

(b) Furnished office space and equipment, including but not being limited to a desk (equipped with a satisfactory locking device), lockers or cabinets suitable for the protection and storage of supplies, and facilities suitable for inspectors to change clothing.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

APPLICATION FOR SERVICE

§ 590.140 How application shall be made.

The proprietor or operator of each plant processing egg products, unless exempted by § 590.100, shall make application to the Administrator for inspection service. The application shall be made in writing on forms furnished by the inspection service. In cases of change of name or ownership or change of location, a new application shall be made.

§ 590.142 Filing of application.

An application for inspection service shall be regarded as filed only when it has been filled in completely and signed by the applicant and has been received in the office of the Chief of the Grading Branch.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.144 Authority of applicant.

Proof of authority of any person applying for inspection service may be required at the discretion of the Administrator.

§ 590.146 Application for continuous inspection in official plants; approval.

Any person desiring to process egg products under continuous inspection service must receive approval of such plant and facilities as an official plant prior to the installation of such service. An application for continuous inspection service to be installed in an official plant shall be approved according to the following procedure:

(a) Initial survey: When an application for continuous inspection in a plant has been filed, a supervisory egg products inspector will make a survey and inspection of the premises and plant to determine if the facilities and methods of operation therein are suitable and adequate for service in accordance with:

(1) These regulations, and

(2) Such other administrative instructions as may be issued from time to time by the Service and which are in

effect at the time of the aforesaid survey and inspection.

(b) Drawings and specifications to be furnished:

(1) Applicants may obtain information or assistance as to the requirements before submitting prints of drawings, specifications, and supplemental information from the inspection service.

(2) Three copies of each print drawing as specified in this section of the complete floor plan, plot plan, supplemental information, and specifications shall be submitted. Sheet size of the print shall not exceed 34 by 44 inches, the wording shall be legible, all lines sharp and clear, and properly drawn to scale. Each print shall show the scale used, north point of the compass, and the firm name, street, city, state, and zip code or an accurate description of the location.

(3) Plot plan of entire premises shall include location of all buildings, railroads, roadways, alleys, wells, reservoirs, drains, catch basins, nearby buildings adjoining property, drainage and slope of terrain, character and surfacing of roadways, driveways, and vehicular loading areas. The plot plan may be drawn to a scale of one-thirty-second inch per foot.

(4) Floor plan prints shall include all space on each floor of the official plant, accurately illustrating and describing the facilities. Detailed drawings of processing area shall be drawn to a scale of one-fourth inch per foot. Prints showing only nonprocessing areas may be drawn to a scale of one-eighth inch per foot.

(5) Floor plans shall show the location of such features as walls, partitions, posts, doorways, windows, floor drains and channel drains, air systems, ventilation fans, principal pieces of equipment, storage tanks, hose connections for cleaning purposes, hand-washing facilities, lockers, and toilets. The prints shall show slope of floors to drains.

(6) The official plant shall include all processing rooms and other rooms used in the official plant, including but not being limited to the breaking room, equipment washing and sanitizing rooms, shell egg washing rooms, packaging rooms, shell egg and egg products storage rooms (including coolers, freezers, hot rooms), drying rooms, toilet and dressing rooms, storerooms for supplies, and all other rooms, compartments, or passageways where products or any ingredients to be used in the preparation of products under this service will be handled or kept and may include other rooms located in the building comprising the official plant. Except in public warehouses, all rooms, compartments, etc., of the building not to be considered as part of the official plant shall not have direct access into any part of the official plant.

(7) Supplemental information may be shown as notations on the drawings or on supplemental sheets. Supplemental information shall include clarifying information such as sequence of processing edible products, handling of inedible product, shell disposal, handling of packaging material, liquid pumping systems, cleaned-in-place systems, description of pasteurizer, description of drier, type and efficiency of air filtration, hot water facilities, sewage disposal, and such other notations as may be required.

(8) Specification sheets shall include height of ceilings and type construction, type of floors, and wall construction, wall and partition material, and number of employees who will use each toilet room and facilities.

(c) Upon approval of the prints of drawing, supplemental information, and specifications, the application for service may be approved.

(d) Changes and revisions of official plant: When changes are planned in official plant construction, facilities, and equipment covered by previously approved prints, revised prints shall be submitted for review and approval prior to making the changes by: A completely revised sheet(s) showing proposed alterations and additions or an overlay print drawn to same scale as print to be modified or revised. A final survey of the completed alterations and additions shall be made by the supervisory egg products inspector to determine if the changes are in accordance with approved drawings and the regulations.

(e) Final survey and plant approval: Prior to the inauguration of continuous inspection service, a final survey

of the plant and premises shall be made by the supervisory egg products inspector to determine if the plant is constructed and facilities are installed in accordance with the approved drawings and these regulations. The plant may be approved only when these requirements have been met.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.148 Order of service.

Inspection service shall be performed, insofar as practicable, in the order in which applications therefor are made.

[36 FR 9814, May 28, 1971, as amended at 42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

INAUGURATION OF SERVICE

§ 590.150 Official plant numbers.

An official plant number shall be assigned to each plant granted inspection service. Such plant number shall be used to identify all containers of inspected products prepared in the plant which are capable of use as human food. A plant shall not have more than one plant number.

§ 590.155 Inauguration of service.

Prior to the inauguration of service, the proprietor or operator of the plant shall be knowledgeable of the requirements of these regulations.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

DENIAL OF SERVICE

§ 590.160 Refusal, suspension, or withdrawal of service.

(a) The Administrator (for such period, or indefinitely, as he deems necessary to effectuate the purposes of the Act) may refuse to provide or may withdraw inspection service under this part with respect to any plant if he determines after opportunity for a hearing (following the procedures of 7 CFR, part 1, subpart H) is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection under the Act or this part, because the applicant or recipient or anyone responsibly connected with such person has been convicted in any Federal or State court, within the previous 10 years, of (1) any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food or fraud in connection with transactions in food or (2) any felony, involving, fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health.

(b) For the purpose of this section, a person shall be deemed to be responsibly connected with the business if he is a partner, officer, director, holder, or owner of 10 percentum or more of its voting stock, or employee in a managerial or executive capacity.

(c) The determination and order of the Administrator with respect thereto under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within 30 days after the effective date of such order in the U.S. Court of Appeals for the circuit in which such applicant or recipient has its principal place of business or in the U.S. Court of Appeals for the District of Columbia Circuit. Judicial review of any such order shall be upon the record upon which the determination and order are based. The provisions of section 204 of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 194) shall be applicable to appeals taken under this section. This section shall not affect in any way other provisions of the Act or these regulations for refusal of inspection services.

(d) Any applicant for inspection at a plant where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 401(a)(1) (33 U.S.C. 1341) of the Clean Water Act as amended (86 Stat. 816, 91 Stat. 1566; 33 U.S.C. 1251 *et seq.*), to provide the Administrator with a certification, as prescribed in said subsection, that any such discharge will comply with the

applicable provisions of sections 301, 302, 303, 306, and 307 of the Act (33 U.S.C. 1311, 1312, 1313, 1316, and 1317). No grant of inspection can be issued unless such certification has been obtained, or is waived, because of failure or refusal of the State, interstate agency, or the Administrator of the Environmental Protection Agency to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request). Further, upon receipt of an application for inspection and a certification as required by subsection 401(a)(1) of the Clean Water Act, the Administrator (as defined in § 590.5) is required by subparagraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that subsection. No grant of inspection can be made until the requirements of 401(a)(1) and (2) have been met.

(e) Inspection may be suspended or revoked and plant approval terminated as provided in subsection 401(a) (4) and (5) of the Clean Water Act, as amended (33 U.S.C. 1341(a) (4) and (5)).

(f) Suspension of plant approval and withdrawal of service:

(1) Any plant approval given pursuant to these regulations may be suspended by the Administrator for (i) failure to maintain premises, facilities, and equipment in a satisfactory state of repair; (ii) the use of operating procedures or practices which are not in accordance with the regulations; (iii) the alterations of buildings, facilities, or equipment which have not been approved in accordance with the regulations; or (iv) assaulting, intimidating, impeding, obstructing, or interfering with any person engaged in or on account of the performance of his official duties.

(2) During such period of suspension, no processing of egg products for commerce shall be carried on in the official plant. If the plant facilities or methods of operation are not brought into compliance within a reasonable period of time, to be specified by the Administrator, inspection service shall be withdrawn from the official plant. Upon withdrawal of inspection service in an official plant, the plant approval for processing egg products shall also become terminated.

(3) The operator shall be notified of the withdrawal action and the reasons therefor and afforded an opportunity to present his views informally prior to the effective date of such withdrawal, and upon written request, he shall be afforded an opportunity for a hearing in accordance with the applicable rules of practice (7 CFR, part 1, subpart H), with respect to the merits or validity of the withdrawal, but such a suspension or other withdrawal shall continue in effect pending the outcome of any such hearing unless otherwise ordered by the Administrator.

(4) In any case where inspection service is suspended under this paragraph (f) of this section, such service, after appropriate corrective action is taken, will be restored immediately, or as soon thereafter as an inspector can be made available. In any case where inspection service is withdrawn for a specified period under this paragraph (f) of this section, the person concerned may, after said specified period has expired, apply for inspection service as provided in §§ 590.140 through 590.146.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978; 45 FR 23640, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.161 Termination of plant approval.

When inspection service is not performed at any plant for a period of at least 90 days, plant approval shall terminate upon notice by the Administrator without further proceedings; provided, however, that this section shall not apply to any plant where the Administrator determines that such a plant operates on a seasonal basis and the inspection service has not been used as a result of such seasonal operation, or where operations have ceased due to extraordinary circumstances determined by the Administrator as not warranting termination of plant approval.

[45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

RECORDS AND RELATED REQUIREMENTS FOR EGGS AND EGG PRODUCTS HANDLERS AND RELATED INDUSTRIES

§ 590.200 Records and related requirements.

(a) Persons engaged in the business of transporting, shipping, or receiving any eggs or egg products in commerce, or holding such articles so received, and all egg handlers, including hatcheries, shall maintain records showing, for a period of 2 years, to the extent that they are concerned therewith, the receipt, delivery, sale, movement, and disposition of all eggs and egg products handled by them, and shall, upon the request of an authorized representative of the Secretary, permit him, at reasonable times, to have access to and to copy all such records.

(b) Production records by categories of eggs such as graded eggs, nest-run eggs, dirties, checks, leakers, loss, inedible, etc., bills of sale, inventories, receipts, shipments, shippers, receivers, dates of shipment and receipt, carrier names, etc., as determined by the Administrator, shall be maintained by all egg processing operations, except that, official egg products plants which use all shell eggs received and do not reship any shell eggs need only to maintain records indicating the amount of eggs received, date received, and the name and address of the shipper.

[37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 63 FR 69971, Dec. 17, 1998]

§ 590.220 Information and assistance to be furnished to inspectors.

When inspection service is performed at any plant, the plant operator shall furnish the inspector such information and assistance as may be required for the performance of inspection functions, preparing certificates, reports, and for other official duties.

ADMINISTRATIVE DETENTION

§ 590.240 Detaining product.

Whenever any eggs or egg products subject to the Act are found by any authorized representative of the Secretary upon any premises, and there is reason to believe that they are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of the Act or the regulations in this part, or that they are in any other way in violation of the Act, such articles may be detained by such representative for a period not to exceed 20 days, as more fully provided in section 19 of the Act. A detention tag or other similar device shall be used to identify detained product, and the custodian or owner shall be given a written notice of such detention. Only authorized representatives of the Secretary shall affix or remove detention identification. The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of the Act, the regulations in this part, or other laws.

[37 FR 6658, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69972, Dec. 17, 1998]

APPEAL OF AN INSPECTION OR DECISION

§ 590.300 Who may request an appeal inspection or review of an inspector's decision.

Any appeal inspection may be requested by any interested party who is dissatisfied with the determination by an inspector of the class, quantity, or condition of any product, and a review may be requested by the operator of an official plant with respect to an inspector's decision or on any other matter related to inspection in the official plant.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

§ 590.310 Where to file an appeal.

(a) *Appeal of resident inspector's inspection or decision in an official plant.* Any interested party who is not satisfied with the determination of the class, quantity, or condition of product which was inspected by an inspector in an official plant and has not left such plant, and the operator of any official

plant who is not satisfied with a decision by an inspector on any other matter relating to inspection in such plant may request an appeal inspection or review of the decision by the inspector by filing such request with the inspector's immediate supervisor.

(b) *All other appeal requests.* Any interested party who is not satisfied with the determination of the class, quantity, or condition of product which has left the official plant where it was inspected may request an appeal inspection by filing such request with the Regional Director in the region where the product is located or with the Chief of the Grading Branch.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§ 590.320 How to file an appeal.

The request for an appeal inspection or review of an inspector's decision may be made orally or in writing. If made orally, written confirmation may be required. The applicant shall clearly state the identity of the product, the decision which is questioned, and the reason(s) for requesting the appeal service. If such appeal request is based on the results stated on an official certificate, the original and all copies of the certificate available at the appeal inspection site shall be provided to the inspector assigned to make the appeal inspection.

[60 FR 49169, Sept. 21, 1995]

§ 590.330 When an application for an appeal inspection may be refused.

When it appears to the official with whom an appeal request is filed that the reasons given in the request are frivolous or not substantial, or that the condition of the product has undergone a material change since the original inspection, or that the original lot has changed in some manner, or the Act or the regulations in this part have not been complied with, the applicant's request for the appeal inspection may be refused. In such case, the applicant shall be promptly notified of the reason(s) for such refusal.

[60 FR 49169, Sept. 21, 1995, as amended at 63 FR 69972, Dec. 17, 1998]

§ 590.340 Who shall perform the appeal.

(a) An appeal inspection or review of a decision requested under § 590.310(a) shall be made by the inspector's immediate supervisor or by a licensed inspector assigned by the immediate supervisor other than the inspector whose inspection or decision is being appealed.

(b) The assignment of the inspector(s) who will make the appeal inspection under § 590.310(b) shall be made by the Regional Director or the Chief of the Grading Branch, Poultry Division, Agricultural Marketing Service.

§ 590.350 Procedures for selecting appeal samples.

(a) *Prohibition on movement of product.* Products shall not have been moved from the place where the inspection being appealed was performed and must have been maintained under adequate refrigeration when applicable.

(b) *Laboratory analyses.* The appeal sample shall consist of product taken from the original sample containers plus an equal number of containers selected at random. When the original sample containers cannot be located, the appeal sample shall consist of product taken at random from double the number of original sample containers.

(c) *Condition inspection.* The appeal sample shall consist of product taken from the original sample containers plus an equal number of containers selected at random. A condition appeal cannot be made unless all originally sampled containers are available.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

§ 590.360 Appeal inspection certificates.

Immediately after an appeal inspection is completed, an appeal certificate shall be issued to show that the original inspection was sustained or was not sustained. Such certificate shall supersede any previously issued certificate

for the product involved and shall clearly identify the number and date of the superseded certificate. The issuance of the appeal certificate may be withheld until any previously issued certificate and all copies have been returned when such action is deemed necessary to protect the interest of the Government. When the appeal inspector assigns a different class to the lot or determines that a net weight shortage exists, the lot shall be retained pending correction of the labeling or approval of the product disposition by the National Supervisor.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

§ 590.370 Cost of appeals.

(a) There shall be no cost to the appellant when the appeal inspection discloses a material error was made in the original determination.

(b) The costs of an appeal shall be borne by the appellant at an hourly rate of $27.36, including travel time and expenses if the appeal was frivolous, including but not being limited to the following: The appeal inspection discloses that no material error was made in the original inspection, the condition of the product has undergone a material change since the original inspection, the original lot has changed in some manner, or the Act or these regulations have not been complied with.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 46 FR 49571, Oct. 7, 1981. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 58 FR 57539, Oct. 26, 1993; 59 FR 52636, Oct. 18, 1994]

CERTIFICATES

§ 590.400 Form of certificates.

All certificates shall be issued on forms approved by the Administrator.

§ 590.402 Egg products inspection certificates.

(a) Upon request of the applicant or the Service, any inspector is authorized to issue an egg products inspection certificate with respect to any lot of egg products inspected by him. In addition, an inspector is authorized to issue an inspection certificate covering product inspected in whole or in part by another inspector when the inspector has knowledge that the product is eligible for certification based on personal examination of the product or official inspection records.

(b) Each egg products inspection certificate shall show the name and address of the processor, the class and quantity of the egg products covered by such certificate, such shipping marks as are necessary to identify such products, all pertinent information concerning the wholesomeness thereof, and such other information as the Administrator may prescribe or approve.

§ 590.404 Erasures or alterations made on official certificates.

Erasures or alterations shall be initialed by the issuing inspector on the original certificate and any copy thereof. All certificates made useless through clerical error or otherwise and all certificates canceled for whatever cause shall be voided and initialed and the original and all other copies shall be forwarded as prescribed by the Administrator.

§ 590.406 Disposition of official certificates.

The original and up to two copies of each official certificate shall be issued to the applicant or person designated by him. Other copies shall be filed and retained in accordance with the disposition schedule for inspection program records.

§ 590.407 Export certification and marking of containers with export inspection mark.

(a) Exporters must apply for export certification of inspected and passed products shipped to any foreign country. Exporters may apply for an export certificate using a paper or electronic application. FSIS will assess exporters that submit an electronic application the charge in § 592.500(d) of this chapter.

(b) FSIS will issue only one certificate for each consignment, except in the case of error in the certificate or loss of the certificate originally issued. A request for a replacement certificate, except in the case of a lost certificate,

must be accompanied by the original certificate. The new certificate will carry the following statement: ''Issued in replacement of _____'', with the numbers of the certificates that have been superseded.

(c) FSIS will deliver a copy of the export certificate to the person who requested such certificate or his agent. Such persons may duplicate the certificate as required in connection with the exportation of the product.

(d) FSIS will retain a copy of the certificate.

(e)(1) When authorized by inspection personnel, establishments must mark the outside container of any inspected and passed egg products destined for export, the securely enclosed pallet within the consignment, or closed means of conveyance transporting the consignment, with a mark that contains a unique identifier that links the consignment to the export certificate or an official mark with the following form:[1]

(2) Ship stores, small quantities exclusively for the personal use of the consignee and not for sale or distribution, and shipments by and for the U.S. Armed Forces, are exempt from the requirements of this section.

(f) Exporters may request inspection personnel to issue certificates for export consignments of product of official establishments not under their supervision, provided the consignments are first identified as having been ''U.S. inspected and passed,'' are found to be neither adulterated nor misbranded, and are marked as required by paragraph (e) of this section.

[81 FR 42235, June 29, 2016]

[1]The number ''1234567'' is given as an example only. The number on the export certificate will correspond to the printed number on the export certificate.

IDENTIFYING AND MARKING PRODUCT

§ 590.410 Shell eggs and egg products required to be labeled.

(a) All shell eggs packed into containers destined for the ultimate consumer shall be labeled to indicate that refrigeration is required, e.g., ''Keep Refrigerated,'' or words of similar meaning.

(b) Containers and portable tanks of edible egg products, prior to leaving the official plant, shall be labeled in accordance with §§ 590.411 through 590.415 and shall bear the official identification shown in Figure 2 of § 590.412 or Figure 3 or 4 of § 590.415. Bulk transport shipments of liquid pasteurized egg products to nonofficial outlets need not be sealed. Bulk shipments of liquid egg products transported from one official plant to another shall be sealed and accompanied by an official certificate.

[40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 45675, Aug. 27, 1998]

§ 590.411 Requirement of formulas and approval of labels for use in official egg products plants.

(a) No label, container, or packaging material which bears official identification may bear any statement that is false or misleading. Any label, container, or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe. No label, container, or packaging material bearing official identification may be used unless it is approved by the Administrator in accordance with paragraph (b) of this section. The use of finished labels must be approved as prescribed by the Administrator. If the label is printed on or otherwise applied directly to the container or packaging material, the principal display panel thereof shall be considered as the label.

(b) No label, container, or packaging material bearing official identification may be printed or prepared for use until the printers' or other final proof has been approved by the Administrator in accordance with the regulations in this part, the Egg Products Inspection Act, the Federal Food, Drug,

and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations promulgated under these acts. Copies of each label submitted for approval shall be accompanied by:

(1) A statement showing by their common or usual names the kinds and percentages of the ingredients comprising the egg product. A range may be given in cases where the percentages may vary from time to time. Formulas are to be expressed in terms of a liquid product except for products which are dry blended. Also, for products to be dried, the label may show the ingredients in the order of descending proportions by weight in the dried form. However, the formula submitted must include the percentage of ingredients in both liquid and dried form.

(2) When required, scientific data demonstrating that the substance or mixture is safe and effective for its intended use and does not promote deception or cause the product to be otherwise adulterated or misbranded.

(c) Containers of product bearing official identification shall display the following information:

(1) The common or usual name, if any, and if the product is comprised of two or more ingredients, such ingredients shall be listed in the order of descending proportions by weight in the form in which the product is to be marketed (sold), except that ingredients in dried products (other than dry blended) may be listed in either liquid or dried form. When water (excluding that used to reconstitute dehydrated ingredients back to their normal composition) is added to a liquid or frozen egg product or to an ingredient of such products (in excess of the normal water content of that ingredient), the total amount of water added, including the water content of any cellulose or vegetable gums used, shall be expressed as a percentage of the total product weight in the ingredient statement on the label.

(2) The name, address, and ZIP code of the packer or distributor. When the distributor is shown, it shall be qualified by such terms as ''packed for,'' ''distributed by,'' or ''distributors'';

(3) The lot number or approved alternative code number indicating date of production;

(4) The net contents;

(5) Official identification and plant number;

(6) Egg products which are produced in an official plant from edible shell eggs of other than current production or from other egg products produced from shell eggs of other than current production, shall be clearly and distinctly labeled in close proximity to the common or usual name of the product, e.g., ''Manufactured from eggs of other than current production'';

(7) Egg products produced from edible shell eggs or the egg product produced from such shell eggs of the turkey, duck, goose, or guinea shall be clearly and distinctly labeled as to the common or usual name of the product indicating the type of eggs or egg products used in the product, e.g., ''Frozen whole turkey eggs,'' ''Frozen whole chicken and turkey eggs.'' Egg products labeled without qualifying words as to the type of shell egg used in the product shall be produced only from the edible shell egg of the domesticated chicken or the egg product produced from such shell eggs.

(d) Liquid or frozen egg products identified as whole eggs and prepared other than in natural proportions, as broken from the shell, shall have a total egg solids content of 24.20 percent or greater.

(e) Nutrition information may be included on labels used to identify egg products, providing such labeling complies with the provisions of 21 CFR part 101, promulgated under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Since these regulations have different requirements for consumer packaged products than for bulk packaged egg products not for sale or distribution to household consumers, label submission shall be accompanied with information indicating whether the label covers consumer packaged or bulk packaged product. Nutrition labeling is required when nutrients, such as proteins, vitamins, and minerals are added to the product, or when a nutritional claim or information is presented on the labeling, except for the following which are exempt from nutrition labeling requirements:

(1) Egg products shipped in bulk form for use solely in the manufacture of

other food and not for distribution to household consumers in such bulk form or containers.

(2) Products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label, or in advertising, which is supplied for institutional food use only: *Provided*, That the manufacturer or distributor provides the required nutrition information directly to those institutions.

(3) Any nutrient(s) included in product solely for technological purpose may be declared solely in the ingredients statement, without complying with nutrition labeling, if the nutrient(s) is otherwise not referred to in labeling or in advertising. All labels showing nutrition information or claims are subject to review by the Food and Drug Administration prior to approval by the Department.

(f) If the Administrator has reason to believe that the statement on formulation shows the product to be adulterated or misbranded or that any labeling, or the size or form of any container in use or proposed for use in respect to egg products at any official plant is false or misleading in any way, he may direct that such use be withheld unless the labeling or container is modified in such a manner as he may prescribe so that it will not be false or misleading, and/or the formulation of the product is altered in such a manner that he may prescribe so that it is not adulterated, or would not cause misbranding. Any person so denied the approval of any label shall be notified promptly of the reasons for the denial on a form approved by the Administrator. If the person using or proposing to use the label does not accept the determination of the Administrator, he may request a hearing by filing with the Administrator within 10 days after receiving the notice of denial, a written application for a hearing setting forth specifically, the errors alleged to have been made by the Administrator in denying approval of the label. The use of the label shall be withheld pending hearing and final determination by the Administrator if the Administrator so directs. Hearings held pursuant to this subsection shall be presided at by the Administrator. The applicant shall be given the opportunity to present evidence both oral and written in support of his allegation that the Administrator erred in denying approval of the label. The notice of denial together with all other available data and information used as a basis for such denial shall be considered part of the record. The Administrator may take official notice of such matters as are judicially noticed by the Courts of the United States and of any other matter of technical, scientific, or commercial fact of established character. The Administrator shall make his final determination with respect to the matter upon the basis of evidence before him. Such determination shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

[37 FR 6658, Apr. 1, 1972, as amended at 40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 53 FR 23751, June 24, 1988; 60 FR 49169, Sept. 21, 1995]

§ 590.412 Form of official identification symbol and inspection mark.

(a) The shield set forth in Figure 1 containing the letters ''USDA'' shall be the official identification symbol for purposes of this part and, when used, imitated, or simulated in any manner in connection with a product, shall be deemed to constitute a representation that the product has been officially inspected.

(b) The inspection mark which is to be used on containers of edible egg products shall be contained within the outline of a shield and with the wording and design set forth in Figure 2 of this section, except the plant number may be preceded by the letter ''P'' in lieu of the word ''plant''. Alternatively, it may be omitted from the official shield if applied on the container's

principal display panel or other prominent location and preceded by the letter ''P'' or the word ''Plant''.

FIGURE 1.

FIGURE 2.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.414 Products bearing the official inspection mark.

Egg products which are permitted to bear the inspection mark shall be processed in an official plant from edible shell eggs or other edible egg products and may contain other edible ingredients. The official mark shall be printed or lithographed and applied as a part of the principal display panel of the container but shall not be applied to a detachable cover.

§ 590.415 Use of other official identification.

Other official identification as shown in this section shall be printed or lithographed and applied as a part of the principal display panel, but shall not be applied to a detachable cover. The plant number may be omitted from the identification if applied elsewhere on the container's principal display panel or other prominent location and preceded by the letter ''P'' or the word ''plant''. Such products shall meet all requirements for egg products which are permitted to bear the official inspection mark shown in § 590.412, except for pasteurization, heat treatment, or other such methods of treatment approved by the Administrator. Such products shall not be released into consuming channels until they have been subjected to pasteurization, heat treatment, or other approved methods of treatment.

(a) All nonpasteurized egg products, except as provided in paragraph (b) of this section, shipped from an official plant in packaged form shall be marked with the identification set forth in Figure 3 of this section. After pasteurization or treatment, the product may bear the official inspection mark as shown in § 590.412.

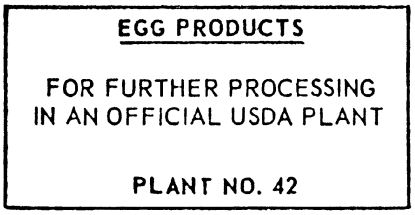


FIGURE 3.

(b) All nonpasteurized egg products, containing 10 percent or more added salt, shipped from an official plant in packaged form to an acidic dressing manufacturer shall be marked with the identification set forth in Figure 4 of this section.

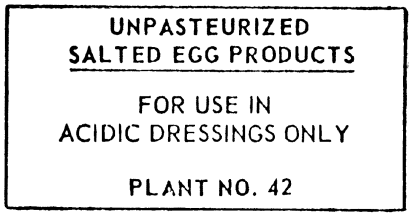


FIGURE 4.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.417 Unauthorized use or disposition of approved labels.

(a) Containers or labels which bear official identification approved for use pursuant to § 590.411 shall be used only for the purpose for which approved. Any unauthorized use or disposition of approved containers or labels which bear any official identification may result in cancellation of the approval and denial of the use of containers or labels bearing official identification and may subject such violator to the penalties and denial of the benefits of the Act;

(b) The use of simulations or imitations of any official identification by any person is prohibited;

(c) Upon termination of inspection service in an official plant pursuant to these regulations, all labels or packaging materials indicating product packed by the plant which bear official identification shall either be destroyed under the supervision of the Service or, if used in another location, modified in a manner acceptable to the Service before use.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975; 42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.418 Supervision of marking and packaging.

(a) *Evidence of label approval.* No inspector shall authorize the use of official identification on any inspected product unless he has on file evidence that such official identification or packaging material bearing such official identification has been approved in accordance with the provisions of § 590.411.

(b) *Affixing of official identification.* No official identification shall be, or caused to be affixed to or placed on any product or container except by an inspector or under the supervision of an inspector or other person authorized by the Administrator. All such products shall have been inspected in accordance with these regulations. The inspector shall have supervision over the use and handling of all material bearing any official identification.

(c) *Labels for products sold under Government contract.* The inspector in the official plant may approve use of labels for containers of product sold under a contract specification to governmental agencies when such product is not offered for resale to the general public: *Provided,* That the contract specifications have been approved by the Administrator and include complete specific requirements with respect to labeling and are made available to the inspector.

§ 590.419 Reuse of containers bearing official identification prohibited.

The reuse, by any person, of containers bearing official identification is prohibited unless such identification is applicable in all respects to product being packed therein. In such instances, the container and label may be used provided the packaging is accomplished under the supervision of an inspector and the container is in compliance with § 590.504(k).

INSPECTION, REINSPECTION, CONDEMNATION, AND RETENTION

§ 590.420 Inspection.

(a) Continuous inspection shall be made, pursuant to these regulations, of the processing of egg products in each official plant processing egg products for commerce unless exempted under § 590.100. Inspections, certifications, or specification-type gradings, and other inspections which may be requested by the official plant and are in addition to the normal inspection requirements and functions for the processing, production, or certification of a wholesome egg product under this part, shall

be made pursuant to the voluntary egg products inspection service (part 55 of this chapter).

(b) Any food manufacturing establishment or institution which uses any eggs that do not meet the requirements of § 590.100(a) in the preparation of any articles for human food shall be deemed to be a plant processing egg products requiring continuous inspection under this part.

(c) Any product which is prepared under inspection in an official plant shall be inspected in such plant as often as the inspector deems necessary in order to ascertain if the product is unadulterated, wholesome, properly labeled, and fit for human food at the time it leaves the plant. Upon any such inspection, if any product or portion thereof is found to be adulterated, unwholesome, or otherwise unfit for human food, such product or portion thereof shall be condemned and shall receive such treatment as provided in § 590.422.

§ 590.422 Condemnation.

Eggs and egg products found to be adulterated at official plants shall be condemned and, if no appeal be taken from such determination of condemnation, such articles shall be destroyed for human food purposes under the supervision of an inspector: *Provided,* That articles which may by reprocessing be made not adulterated need not be condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated. If an appeal is requested, the eggs or egg products shall be appropriately marked and segregated pending completion of an appeal inspection. The appeal shall be at the cost of the appellant if the Administrator determines that the appeal is frivolous, as defined in § 590.370.

§ 590.424 Reinspection.

(a) No egg product may be brought into an official plant except as provided in § 590.430(b) unless it has been prepared and handled in accordance with these regulations, and the container of such product is marked so as to identify the article as so inspected in accordance with this part.

(b) All egg products shall be reinspected by an inspector at the time they are brought into the official plant. Upon reinspection, if any such product or portion thereof is found to be unsound, unwholesome, adulterated, or otherwise unfit for human food, such product or portion thereof, shall be condemned and shall receive such treatment as provided in § 590.422, and shall, in the case of other products be disposed of according to applicable law.

§ 590.426 Retention.

Retention tags or other devices and methods as may be approved by the Administrator shall be used for the identification and control of products which are not in compliance with the regulations or are held for further examination, and any equipment, utensils, rooms or compartments which are found to be unclean or otherwise in violation of the regulations. No product, equipment, utensil, room, or compartment shall be released for use until it has been made acceptable. Such identification shall not be removed by anyone other than an inspector.

Entry of Material Into Official Egg Products Plants

§ 590.430 Limitation on entry of material.

(a) The Administrator shall limit the entry of eggs and egg products and other materials into official plants under such conditions as he may prescribe to assure that allowing the entry of such articles will be consistent with the purposes of the Act and these regulations.

(b) Inedible egg products may be brought into an official plant for storage and reshipment: *Provided,* they are handled in such a manner that adequate segregation and inventory controls are maintained at all times. Inedible egg products may be processed in official plants: *Provided,* That prior approval is obtained from the Administrator and under such conditions and time limitations as the Administrator may specify. The processing of inedible egg products shall be done under conditions which will not affect the processing of edible products, such as processing in separate areas, or at times

when no edible product is being processed. All equipment and processing areas must be thoroughly cleaned and sanitized prior to processing any edible product.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.435 Wholesomeness and approval of materials.

(a) Substances and ingredients used in the manufacture or preparation of any egg product capable of use as human food shall be clean, wholesome, and unadulterated.

(b) The use of chemical additives in egg products shall be permitted only when they are approved by the Administrator. The Administrator may require, in addition to listing the ingredients, a declaration of the additive, and the purpose of its use.

(c) Chemical additives to be used in the preparation of egg products will be approved only if they comply with the following criteria:

(1) The additive shall be safe under the conditions of its intended use.

(2) The additive shall not promote deception or cause the product to be otherwise adulterated or unwholesome. Scientific data acceptable to the Administrator showing that the additive meets the criteria specified in this paragraph (c) shall be submitted by the person interested in having the additive approved.

(d) Containers and packing or packaging materials in which shell eggs are received into the official plant shall be free from odors and materials which could contaminate or adulterate the eggs or egg products.

§ 590.440 Processing ova.

(a) Ova from slaughtered poultry may be brought into the official plant for processing: *Provided*, That the ova is from wholesome poultry inspected in a plant operating under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) and such product is harvested in a sanitary manner, properly handled, cooled, packaged and labeled: *And provided further*, That such product is wholesome and the containers of such product bear official identification which assures the provisions of this paragraph have been met.

(b) The ova and products containing ova shall be processed, cooled, and pasteurized in the official plant in the same manner as liquid, frozen, or dried yolk products.

(c) The labeling for all products containing ova shall be approved by the Administrator prior to use.

SANITARY, PROCESSING, AND FACILITY REQUIREMENTS

§ 590.500 Plant requirements.

(a) The plant shall be free from objectionable odors, dust, and smokeladen air.

(b) The premises shall be free from refuse, rubbish, waste, and other materials and conditions which constitute a source of odors or a harbor for insects, rodents, and other vermin.

(c) The buildings shall be of sound construction and kept in good repair to prevent the entrance or harboring of vermin.

(d) Rooms shall be kept free from refuse, rubbish, waste materials, odors, insects, rodents, and from any conditions which may constitute a source of odors or engender insects and rodents. Materials and equipment not currently needed shall be handled or stored in a manner so as not to constitute a sanitary hazard.

(e) Doors and windows that open to the outside shall be protected against the entrance of flies and other insects. Doors and windows serving rooms where edible product is exposed shall be so designed and installed to prevent the entrance of dust and dirt. Doors leading into rooms where edible product is processed shall be of solid construction and such doors, other than freezer and cooler doors, shall be fitted with self-closing devices.

(f) Doors and other openings which are accessible to rodents shall be of rodent-proof construction.

(g) There shall be an efficient drainage and plumbing system for the plant and premises. Drains and gutters shall be properly installed with approved traps and vents. The sewage system shall have adequate slope and capacity to readily remove waste from the various processing operations. Floor

drains shall be equipped with traps, and constructed so as to minimize clogging. In new or remodeled construction the drainage systems from toilets and laboratories shall not be connected with other drainage systems within the plant.

(h) The water supply (both hot and cold) shall be ample, clean, and potable, with adequate pressure and facilities for its distribution throughout the plant or portion thereof utilized for egg processing and handling operations and protected against contamination and pollution. A water report, issued under the authority of a State or municipal health agency, certifying to the potability of the water supply shall be obtained by the applicant and furnished to the Administrator whenever such report is required by the Administrator.

(i) The floors, walls, ceiling, partitions, posts, doors, and other parts of all structures shall be of such materials, construction, and finish to permit their ready and thorough cleaning. The floors and curbing shall be watertight.

(j) Each room and each compartment in which any shell eggs or egg products are handled or processed shall be so designed, constructed, and maintained to insure processing and operating conditions of a clean and orderly character, free from objectionable odors and vapors, and maintained in a clean and sanitary condition.

(k) Every precaution shall be taken to exclude dogs, cats, and vermin (including, but not being limited to, rodents and insects) from the plant, or portion thereof utilized in which shell eggs or egg products are handled or stored.

(l)(1) There shall be a sufficient number of adequately lighted dressing rooms and toilet rooms, ample in size, conveniently located and separated from the rooms and compartments in which shell eggs or egg products are handled, processed, or stored. The dressing rooms and toilet rooms shall be separately ventilated, and shall meet all requirements as to sanitary construction and equipment.

(2) The following formula shall serve as a basis for determining the toilet facilities required:

Persons of same sex	Toilet bowls required
1 to 15, inclusive	1
16 to 35, inclusive	2
36 to 55, inclusive	[1] 3
56 to 80, inclusive	[1] 4
For each additional 30 persons in excess of 80	[1] 1

[1] Urinals may be substituted for toilet bowls but only to the extent of one-third of the total number of bowls stated.

(m) Lavatory accommodations (including, but not being limited to, hot and cold running water, single service towels, and soap which does not impart an odor which interferes with accurate evaluation of the product) shall be placed at such locations in the plant to assure cleanliness of each person handling any shell eggs or egg products. The hand washing facilities in the processing areas shall be operated by other than hand operated controls and the drains shall be trapped and connected to the plumbing system.

(n) Suitable facilities for cleaning and sanitizing utensils and equipment shall be provided at convenient locations throughout the plant.

(o) Refuse rooms shall be provided for the accumulation and storage of shells, trash, and other refuse. They shall be separate rooms completely enclosed without doorways opening into breaking rooms or rooms where egg products or packaging materials are handled or stored and have concrete floors with approved drains, facilities for cleaning, and an approved exhaust system vented to the outside. Alternative systems of handling shells, trash, and other refuse may be approved by the Administrator when such systems adequately contain all refuse and provide equivalent sanitary methods for the handling and removal of refuse.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.502 Equipment and utensils; PCB-containing equipment.

(a) Equipment and utensils used in processing shell eggs and egg products shall be of such design, material, and construction as will:

(1) Enable the examination, segregation, and processing of such products in

an efficient, clean, and satisfactory manner;

(2) Permit easy access to all parts to insure thorough cleaning and sanitizing. So far as is practicable, all such equipment shall be made of metal or other impervious material which will not affect the product by chemical action or physical contact.

(b) Except as authorized by the Administrator, in new or remodeled equipment and equipment installations, the equipment and installation shall comply with the applicable 3–A or E–3–A Sanitary Standards and accepted practices currently in effect for such equipment.

(c) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of any official plant shall not contain liquid polychlorinated biphenyls (PCBs) in concentrations above 50 parts per million by weight of the liquid medium. This provision applies to both food processing and nonfood processing equipment and machinery, and any replacement parts for such equipment and machinery. Totally enclosed capacitors containing less than 3 pounds of PCBs are exempted from this prohibition.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 68919, Oct. 17, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.504 General operating procedures.

(a) Operations involving processing, storing, and handling of shell eggs, ingredients, and egg products shall be strictly in accord with clean and sanitary methods and shall be conducted as rapidly as practicable. Pasteurization, heat treatment, stabilization, and other processes shall be in accord with this part and as approved by the Administrator. Processing methods and temperatures in all operations shall be such as will prevent a deterioration of the egg products.

(b) Shell eggs and egg products processed in official plants shall be subjected to constant and continuous inspection throughout each and every processing operation. Any shell egg or egg product which was not processed in accordance with these regulations or is not fit for human food shall be removed and segregated.

(c) All loss and inedible eggs or egg products shall be placed in a container clearly labeled ''inedible'' and containing a sufficient amount of approved denaturant or decharacterant, such as FD&C brown, blue, black, or green colors, meat and fish by-products, grain and milling by-products, or any other substance, as approved by the Administrator, that will accomplish the purposes of this section. Shell eggs shall be crushed and the substance shall be dispersed through the product in amounts sufficient to give the product a distinctive appearance or odor. Notwithstanding the foregoing, and upon permission of the Inspector, the applicant may hold inedible product in containers clearly labeled inedible which do not contain a denaturant if such inedible product is denatured or decharacterized prior to shipment from the official plant: *Provided,* That such product is properly packaged, labeled, segregated, and inventory controls are maintained. In addition, product shipped from the official plant for industrial use or animal food need not be denatured or decharacterized, provided, that such product is properly packaged, labeled, segregated, and inventory controls are maintained, and that such product is shipped under Government seal and certificate and received at the destination location by an inspector or grader as defined in this part.

(d) The inspector may, prior to receipt of laboratory results for salmonella, or for other reasons such as labeling as to solids content, permit egg products to be shipped from the official plant when he has no reason to suspect noncompliance with any of the provisions of this part. However, such shipments shall be made under circumstances which will assure the return of the product to the plant for reprocessing, relabeling, or under such other conditions as the Administrator may determine to assure compliance with this part.

(e) Pasteurizing, stabilizing, or drying operations shall start as soon as practicable after breaking to prevent deterioration of product, preferably

within 72 hours from time of breaking for egg products other than whites which are to be desugared.

(f) Each person who is to handle any exposed or unpacked egg products or any utensils or container which may come into contact with egg product, shall wash his hands and maintain them in a clean condition.

(g) No product or material which creates an objectionable condition shall be processed, stored, or handled in any room, compartment, or place where any shell eggs or egg products are processed, stored or handled.

(h) Only germicides, insecticides, rodenticides, detergents, or wetting agents or other similar compounds which will not deleteriously affect the eggs or egg products when used in an approved manner and which have been approved by the Administrator, may be used in an official plant. The identification, storage, and use of such compounds shall be in a manner approved by the Administrator.

(i) Utensils and equipment which are contaminated during the course of processing any shell eggs or egg products shall be removed from use immediately and shall not be used again until cleaned and sanitized.

(j) Any substance or ingredient added in the processing of any egg products shall be clean and fit for human food.

(k) Packages or containers for egg products shall be of sanitary design and clean when being filled with any egg products; and all reasonable precautions shall be taken to avoid soiling or contaminating the surface of any package or container liner which is, or will be, in direct contact with such egg products. Only new containers or used containers that are clean, in sound condition and lined with suitable inner liners shall be used for packaging edible egg products. Fiber containers used without liners require the approval of the Administrator.

(l) Egg products shall be inspected to determine the wholesomeness of the finished product.

(m) Egg products shall be processed in such a manner as to insure the immediate removal of blood and meat spots, shell particles, and foreign materials.

(n) Utensils and equipment, except drying units, powder conveyors, sifters, blenders, and mechanical powder coolers shall be clean and sanitized at the start of processing operations. Equipment and utensils shall be kept clean and sanitary during all processing operations.

(o) Egg products prior to being released into consuming channels shall be pasteurized in accordance with § 590.570 except that dried whites prepared from nonpasteurized liquid shall be heat treated in accordance with § 590.575.

(1) To assure adequate pasteurization, egg products shall be sampled and tested for the presence of salmonella. Sampling for the presence of salmonella shall be in accordance with § 590.580 and product found to be salmonella positive shall be reprocessed, pasteurized, and analyzed for the presence of salmonella, or denatured.

(2) Nonpasteurized or salmonella positive egg product may be shipped from an official plant only when it is to be pasteurized, repasteurized, or heat treated in another official plant. Shipments of products from one official plant to another for pasteurization, repasteurization, or heat treatment shall be in sealed cars or trucks with an accompanying certificate stating that the product is not pasteurized or is salmonella positive. If nonpasteurized or salmonella positive products are to be stored in other than the official plant facilities, the inspector at the consignee's and consignor's plants shall be given full knowledge of the disposition of the product, including warehouse inventory receipts, until such time as product is pasteurized, repasteurized, or heat treated. The containers of such nonpasteurized or salmonella positive product shall be marked with the identification mark shown in Figure 3 of § 590.415.

(3) Notwithstanding the provision of paragraph (o)(2) of this section, nonpasteurized salted egg products containing 10 percent or more salt added may be shipped from an official plant directly to a manufacturer of acidic dressings only under the following provisions:

(i) Before such shipment is made, the manufacturer of the acidic dressing

shall apply in writing and receive permission from the Administrator to receive and use unpasteurized egg products. The applicant shall sign a written statement containing the specification for the treatment of the nonpasteurized egg product in a manner that will insure that viable salmonella microorganisms are destroyed, and such processing treatment shall be approved by the Administrator prior to use.

(ii) Product shall be shipped under seal from the official plant, accompanied by an official USDA certificate stating that the product is nonpasteurized and for use in acidic dressings only.

(iii) The applicant shall acknowledge receipt of each shipment by indicating on the reverse side of the USDA certificate. ''The quantity of nonpasteurized egg product stated on this certificate was received at _____,'' the blank being filled in with the name and address of the receiving company and the date and signature of the person completing the form. The certificate shall be returned to the USDA inspector at the origin plant.

(iv) The acidic dressing manufacturer shall maintain processing records indicating the use of each shipment of unpasteurized salted product and the code lots of acidic dressing into which it was processed. Records of the pH and the acidity expressed as percent acetic acid of each code lot shall be maintained. The records shall also demonstrate that the acidic dressing was held 72 hours prior to shipment. These records shall be maintained for 2 years and shall be available for inspection by a representative of the Department.

(v) Each container of salted egg product shipped from the official plant shall be labeled as required in § 590.411, and shall bear the words ''Caution—this egg product has not been pasteurized or otherwise treated to destroy viable salmonella microorganisms,'' and shall bear the official identification shown in figure 4 of § 590.415.

(p) Air which is to come in contact with product or with product contact surfaces shall come from approved filtered outside air sources.

(q) All liquid and solid waste material in the official plant shall be disposed of in a manner approved by the Administrator to prevent product contamination and in accordance with acceptable environmental protection practices.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6658, Apr. 1, 1972; 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49170, Sept. 21, 1995]

§ 590.506 Candling and transfer-room facilities and equipment.

(a) The room shall be so constructed that it can be adequately darkened to assure accuracy in removal of inedible or loss eggs by candling. Equipment shall be arranged so as to facilitate cleaning and the removal of refuse and excess packing material.

(b) The construction of the floor shall allow thorough cleaning. The floors shall be of water-resistant composition and provided with proper drainage.

(c) An approved exhaust system shall be provided for the continuous removal directly to the outside of any steam, vapors, odors, or dust in the room. The room shall be maintained at reasonable working temperatures during operations.

(d) Candling devices of an approved type shall be provided to enable candlers to detect loss, inedible, dirty eggs, and eggs other than chicken eggs.

(e) Leaker trays shall be made of a material and of such design that is conducive to easy cleaning and sanitizing.

(f) Containers made of a material and of such design that are conducive to easy cleaning shall be provided for inedible eggs. All such containers shall be conspicuously marked.

(g) Containers made of a material and of such design that are conducive to easy cleaning shall be provided for trash unless clean, disposable containers are furnished daily.

(h) Shell egg conveyors shall be constructed so that they can be thoroughly cleaned.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.508 Candling and transfer-room operations.

(a) Candling and transfer rooms and equipment shall be kept clean, free from cobwebs, dust, objectionable odors, and excess packing materials.

(b) Containers for trash and inedible eggs shall be removed from the candling rooms as often as necessary but at least once daily; and shall be cleaned and treated in such a manner as will prevent off odors or objectionable conditions in the plant.

(c) Shell eggs shall be handled in a manner to minimize sweating prior to breaking.

(d) Shell eggs with extensively damaged shells, unless prohibited under § 590.510(d), shall be placed into leaker trays and shall be broken promptly.

§ 590.510 Classifications of shell eggs used in the processing of egg products.

(a) The shell eggs shall be sorted and classified into the following categories in a manner approved by the National Supervisor:

(1) Eggs listed in paragraph (d) of this section.

(2) Dirty.

(3) Leakers as described in paragraph (c)(2) of this section.

(4) Eggs from other than chicken; duck, turkey, guinea, and goose eggs.

(5) Other eggs—satisfactory for use as breaking stock.

(b) Shell eggs having strong odors or eggs received in cases having strong odors shall be candled and broken separately to determine their acceptability.

(c) Shell eggs, when presented for breaking, shall be of edible interior quality and the shell shall be sound and free of adhering dirt and foreign material, except that:

(1) Checks and eggs with a portion of the shell missing may be used when the shell is free of adhering dirt and foreign material and the shell membranes are not ruptured.

(2) Eggs with clean shells which are damaged in candling and/or transfer and have a portion of the shell and shell membranes missing may be used only when the yolk is unbroken and the contents of the egg are not exuding over the outside shell. Such eggs shall be placed in leaker trays and be broken promptly.

(3) Eggs with meat or blood spots may be used if the spots are removed in an acceptable manner.

(d) All loss or inedible eggs shall be placed in a designated container and be handled as required in § 590.504(c). Inedible and loss eggs for the purpose of this section and § 590.522 are defined to include black rots, white rots, mixed rots, green whites, eggs with diffused blood in the albumen or on the yolk, crusted yolks, stuck yolks, developed embryos at or beyond the blood ring state, moldy eggs, sour eggs, any eggs that are adulterated as such term is defined pursuant to this part, and any other filthy and decomposed eggs including the following:

(1) Any egg with visible foreign matter other than removable blood and meat spots in the egg meat.

(2) Any egg with a portion of the shell and shell membranes missing and with egg meat adhering to or in contact with the outside of the shell.

(3) Any egg with dirt or foreign material adhering to the shell and with cracks in the shell and shell membranes.

(4) Liquid egg recovered from shell egg containers and leaker trays.

(5) Open leakers made in the washing operation.

(6) Any egg which shows evidence that the contents are or have been exuding prior to transfer from the case.

(e) Incubator reject eggs shall not be brought into the official plant.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.515 Egg cleaning operations.

(a) The following requirements shall be met when washing shell eggs to be presented for breaking:

(1) Shell egg cleaning equipment shall be kept in good repair and shall be cleaned after each day's use or more frequently if necessary.

(2) The temperature of the wash water shall be maintained at 90 °F or higher, and shall be at least 20 °F warmer than the temperature of the eggs to be washed. These temperatures

shall be maintained throughout the cleaning cycle.

(3) An approved cleaning compound shall be used in the wash water. (The use of metered equipment for dispensing the compound into solution is recommended.)

(4) Wash water shall be changed approximately every 4 hours or more often if needed to maintain sanitary conditions and at the end of each shift. Remedial measures shall be taken to prevent excess foaming during the egg washing operation.

(5) Replacement water shall be added continuously to the wash water of washers to maintain a continuous overflow. Rinse water and chlorine sanitizing rinse may be used as part of the replacement water. Iodine sanitizing rinse may not be used as part of the replacement water.

(6) Waste water from the egg washing operation shall be piped directly to drains.

(7) The washing operation shall be continuous and shall be completed as rapidly as possible. Eggs shall not be allowed to stand or soak in water. Immersion-type washers shall not be used.

(8) Prewetting shell eggs prior to washing may be accomplished by spraying a continuous flow of water over the eggs in a manner which permits the water to drain away, or by other methods which may be approved by the Administrator.

(b) Shell eggs shall not be washed in the breaking room or any room where edible products are processed.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.516 Sanitizing and drying of shell eggs prior to breaking.

(a) Immediately prior to breaking, all shell eggs shall be spray rinsed with potable water containing an approved sanitizer of not less than 100 ppm nor more than 200 ppm of available chlorine or its equivalent. Alternative procedures may be approved by the Administrator in lieu of sanitizing shell eggs washed in the plant.

(b) Shell eggs shall be sufficiently dry at time of breaking to prevent contamination or adulteration of the liquid egg product from free moisture on the shell.

[60 FR 49170, Sept. 21, 1995]

§ 590.520 Breaking room facilities.

(a) The breaking room shall have at least 30 foot-candles of light on all working surfaces except that light intensity shall be at least 50 foot-candles at breaking and inspection stations. Lights shall be protected with adequate safety devices.

(b) The surface of the ceiling and walls shall be smooth and made of a water-resistant material.

(c) The floor shall be of water-proof composition, reasonably free from cracks or rough surfaces, sloped for adequate drainage, and the intersections with walls and curbing shall be impervious to water.

(d) Ventilation shall provide for:

(1) A positive flow of outside filtered air through the room;

(2) Air of suitable working temperature during operations.

(e) There shall be provided adequate hand washing facilities which are easily accessible to all breaking personnel, an adequate supply of warm water, clean towels or other facilities for drying hands, odorless soap, and containers for used towels. Hand washing facilities shall be operated by other than hand operated controls.

(f) Containers for packaging egg products are not acceptable as liquid egg buckets.

(g) A suitable container conspicuously identified shall be provided for the disposal of rejected liquid.

(h) Strainers, filters, or centrifugal clarifiers of approved construction shall be provided for the effective removal of shell particles and foreign material, unless specific approval is obtained from the National Supervisor for other mechanical devices.

(i) A separate drawoff room with a filtered positive air ventilation system shall be provided for packaging liquid egg product, except product packaged

by automatic, closed packaging systems.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.522 Breaking room operations.

(a) The breaking room shall be kept in a dust-free clean condition and free from flies, insects, and rodents. The floor shall be kept clean and reasonably dry during breaking operations and free of egg meat and shells.

(b) All breaking room personnel shall wash their hands thoroughly with odorless soap and water each time they enter the breaking room and prior to receiving clean equipment after breaking an inedible egg.

(c) Paper towels or tissues shall be used at breaking tables, and shall not be reused. Cloth towels are not permitted.

(d) Breakers shall use a complete set of clean equipment when starting work and after lunch periods. All table equipment shall be rotated with clean equipment every 2½ hours.

(e) Cups shall not be filled to overflowing.

(f) Each shell egg shall be broken in a satisfactory and sanitary manner and inspected for wholesomeness by smelling the shell or the egg meat and by visual examination at the time of breaking. All egg meat shall be reexamined by a person qualified to perform such functions before being emptied into the tank or churn, except as otherwise approved by the National Supervisor.

(g) Shell particles, meat and blood spots, and other foreign material accidentally falling into the cups or trays shall be removed with a spoon or other approved instrument.

(h) Whenever an inedible egg is broken, the affected breaking equipment shall be cleaned and sanitized.

(i) Inedible and loss eggs as defined in § 590.510 apply to this section.

(j) The contents of any cup or other liquid egg receptacle containing one or more inedible or loss eggs shall be rejected.

(k) Contents of drip trays shall be emptied into a cup and smelled carefully before pouring into liquid egg bucket. Drip trays shall be emptied at least once for each 15 dozen eggs or every 15 minutes.

(l) Edible leakers as defined in § 590.510(c)(2) and checks which are liable to be smashed in the breaking operation shall be broken at a separate station by specially trained personnel.

(m) Ingredients and additives used in, or for, processing egg products, shall be handled in a clean and sanitary manner.

(n) Liquid egg containers shall not pass through the candling room.

(o) Test kits shall be provided and used to determine the strength of the sanitizing solution. (See §§ 590.515(a)(9) and 590.552.)

(p) Leaker trays shall be washed and sanitized whenever they become soiled and at the end of each shift.

(q) Shell egg containers whenever dirty shall be cleaned and drained; and shall be cleaned, sanitized, and drained at the end of each shift.

(r) Belt-type shell egg conveyors shall be cleaned and sanitized approximately every 4 hours in addition to continuous cleaning during operation. When not in use, belts shall be raised to permit air drying.

(s) Cups, knives, racks, separators, trays, spoons, liquid egg pails, and other breaking equipment, except for mechanical egg breaking equipment, shall be cleaned and sanitized at least every 2½ hours. This equipment shall be cleaned at the end of each shift and shall be clean and sanitized immediately prior to use.

(t) Utensils and dismantled equipment shall be drained and air dried on approved self-draining metal racks and shall not be nested.

(u) Dump tanks, drawoff tanks, and churns shall be cleaned approximately every 4 hours. All such equipment and all other liquid handling equipment, unless cleaned by acceptable cleaned in-place methods, shall be dismantled and cleaned after each shift. Pasteurization equipment shall be cleaned at the end of each day's use or more often if necessary. All such equipment shall be clean and shall be sanitized prior to placing in use.

(v) Strainers, clarifiers, filtering and other devices used for removal of shell particles and other foreign material

shall be cleaned and sanitized each time it is necessary to change such equipment, but at least once each 4 hours of operation.

(w) Breaking room processing equipment shall not be stored on the floor.

(x) Metal containers and lids for other than dried products shall be thoroughly washed, rinsed, sanitized, and drained immediately prior to filling. The foregoing sequence shall not be required if equally effective measures approved by the National Supervisor in writing are followed to assure clean and sanitary containers at the time of filling.

(y) Liquid egg holding vats and containers (including tank trucks) used for transporting liquid eggs shall be cleaned after each use. Such equipment shall be clean and sanitized immediately prior to placing in use.

(z) Tables, shell conveyors, and containers for inedible egg product shall be cleaned at the end of each shift.

(aa) Mechanical egg breaking machines shall be operated at a rate to maintain complete control and accurately inspect and segregate each egg to insure the removal of all loss and inedible eggs. The machine shall be operated in a sanitary manner.

(1) When an inedible egg is encountered on mechanical egg breaking equipment, the inedible egg and contaminated liquid shall be removed. The machine shall be cleaned and sanitized, or contaminated parts replaced with clean ones in the manner prescribed by the Administrator for the type of inedible egg encountered and the kind of egg breaking machine.

(2) Systems for pumping egg liquid directly from egg breaking machines shall be of approved sanitary design and construction, and designed to minimize the entrance of shells into the system and be disconnected when inedible eggs are encountered. The pipelines of the pumping system shall be cleaned or flushed as often as needed to maintain them in a sanitary condition, and they shall be cleaned and sanitized at the end of each shift. Other pumping system equipment shall be cleaned and sanitized approximately every 4 hours or as often as needed to maintain it in a sanitary condition. All liquid egg pumped directly from egg breaking machines shall be reexamined, except as otherwise prescribed and approved by the Administrator.

(3) Mechanical egg breaking equipment shall be clean and sanitized prior to use, and during operations the machines shall be cleaned and sanitized approximately every 4 hours or more often if needed to maintain them in a sanitary condition. This equipment shall be cleaned at the end of each shift.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972; 40 FR 20059, May 8, 1975; 40 FR 20941, May 14, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.530 Liquid egg cooling.

(a) Liquid egg storage rooms, including surface coolers and holding tank rooms, shall be kept clean and free from objectionable odors and condensation. Surface coolers and liquid holding vats containing product shall be kept covered while in use. Liquid cooling units shall be of approved construction and have sufficient capacity to cool all liquid eggs to the temperature requirements specified in this section.

(b) Compliance with temperature requirements applying to liquid eggs shall be considered as satisfactory only if the entire mass of the liquid meets the requirements.

(c) The cooling and temperature requirements for liquid egg products shall be as specified in Table I of this section.

TABLE I—MINIMUM COOLING AND TEMPERATURE REQUIREMENTS FOR LIQUID EGG PRODUCTS

[Unpasterurized product temperature within 2 hours from time of breaking]

Product	Liquid (other than salt product) to be held 8 hours or less	Liquid (other than salt product) to be held in excess of 8 hours	Liquid salt product	Temperature within 2 hours after pasteurization	Temperature within 3 hours after stabilization
Whites (not to be stabilized)	55 °F. or lower	45 °F. or lower		45 °F. or lower.	
Whites (to be stabilized)	70 °F. or lower	55 °F. or lower		55 °F. or lower	(1)

TABLE I—MINIMUM COOLING AND TEMPERATURE REQUIREMENTS FOR LIQUID EGG PRODUCTS—Continued

[Unpasterurized product temperature within 2 hours from time of breaking]

Product	Liquid (other than salt product) to be held 8 hours or less	Liquid (other than salt product) to be held in excess of 8 hours	Liquid salt product	Temperature within 2 hours after pasteurization	Temperature within 3 hours after stabilization
All other product (except product with 10 percent or more salt added).	45 °F. or lower	40 °F. or lower	.....	If to be held 8 hours or less 45 °F. or lower. If to be held in excess of 8 hours, 40 °F. or lower.	If to be held 8 hours or less, 45 °F. or lower. If to be held in excess of 8 hours, 40 °F. or lower.
Liquid egg product with 10 percent or more salt added.	.....	.....	If to be held 30 hours or less, 65 °F. or lower. If to be held in excess of 30 hours, 45 °F. or lower.	65 °F. or lower[2].	

[1] Stabilized liquid whites shall be dried as soon as possible after removal of glucose. The storage of stabilized liquid whites shall be limited to that necessary to provide a continuous operation.

[2] The cooling process shall be continued to assure that any salt product to be held in excess of 24 hours is cooled and maintained at 45 °F. or lower.

(d) Upon written request and under such conditions as may be prescribed by the National Supervisor, liquid cooling and holding temperatures not otherwise provided for in this section may be approved.

(e) Agitators shall be operated in such a manner as will minimize foaming.

(f) When ice is used as an emergency refrigerant by being placed directly into the egg meat, the source of the ice must be certified by the local or State board of health. Such liquid shall be dried. All ice shall be handled in a sanitary manner.

(g) Previously frozen egg or egg product cannot be added to liquid product for the purpose of complying with liquid cooling requirements.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977 and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49170, Sept. 21, 1995]

§ 590.532 Liquid egg holding.

(a) Tanks and vats used for holding liquid eggs shall be of approved construction, fitted with covers, and located in rooms maintained in a sanitary condition. Notwithstanding the foregoing, tanks designed for installation partially outside of a room or building are acceptable, providing all openings into the tanks terminate in the processing room.

(b) Liquid egg holding tanks or vats shall be equipped with suitable thermometers and agitators.

(c) Inlets to holding tanks or vats shall be such as to prevent excessive foaming.

(d) Gaskets, if used, shall be of a sanitary type.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.534 Freezing facilities.

(a) Freezing rooms, either on or off the premises, shall be capable of freezing all liquid egg products in accordance with the freezing requirements as set forth in § 590.536. Use of off-premise freezing facilities is permitted only when prior approval in writing from the National Supervisor is on file.

(b) Adequate air circulation shall be provided in all freezing rooms.

§ 590.536 Freezing operations.

(a) Freezing rooms shall be kept clean and free from objectionable odors.

(b) Requirements. (1) Nonpasteurized egg products which are to be frozen shall be solidly frozen or reduced to a temperature of 10 °F or lower within 60 hours from time of breaking.

(2) Pasteurized egg products which are to be frozen shall be solidly frozen or reduced to a temperature of 10 °F or lower within 60 hours from time of pasteurization.

(3) The temperature of the products not solidly frozen shall be taken at the center of the container to determine compliance with this section.

(c) Containers shall be stacked so as to permit circulation of air around the containers.

(d) The outside of liquid egg containers shall be clean and free from evidence of liquid egg.

(e) Frozen egg products shall be examined by organoleptic examination after freezing to determine their fitness for human food. Any such products which are found to be unfit for human food shall be denatured and any official identification mark which appears on any container thereof shall be removed or completely obliterated and the containers identified as required in §§ 590.840 and 590.860.

§ 590.538 Defrosting facilities.

(a) Approved metal defrosting tanks or vats constructed so as to permit ready and thorough cleaning shall be provided.

(b) Frozen egg crushers, when used, shall be of approved metal construction. The crushers shall permit ready and thorough cleaning and the bearings and housing shall be fabricated in such a manner as to prevent contamination of the egg products.

(c) Service tables shall be of approved metal construction without open seams and the surfaces shall be smooth to allow thorough cleaning.

§ 590.539 Defrosting operations.

(a) Frozen egg products which are to be defrosted shall be defrosted in a sanitary manner.

(b) Each container of frozen eggs shall be checked for condition and odor just prior to being emptied into the crusher or receiving tank. Frozen eggs which have objectionable odors and are unfit for human food (e.g., sour, musty, fermented, or decomposed odors) shall be denatured.

(c) Frozen whites to be used in the production of dried albumen may be defrosted at room temperature. All other whites shall be defrosted in accordance with paragraph (d) of this section.

(d) Frozen whole eggs, whites and yolks, and yolks may be tempered or partially defrosted for not to exceed 48 hours at a room temperature no higher than 40 °F. or not to exceed 24 hours at a room temperature above 40 °F.: *Provided,* That no portion of the defrosted liquid shall exceed 50 °F. while in or out of the container.

(1) Frozen eggs packed in metal or plastic containers may be placed in running tap water (70 F° or lower) without submersion to speed defrosting.

(2) The defrosted liquid shall be held at 40 °F. or less, except for product to be pasteurized or stabilized by glucose removal as provided in § 590.530. Defrosted liquid shall not be held more than 16 hours prior to processing or drying.

(e) Sanitary methods shall be used in handling containers and removing egg product.

(f) Crushers and other equipment used in defrosting operations shall be dismantled at the end of each shift and shall be washed, rinsed, and sanitized.

(1) Where crushers are used intermittently, they shall be flushed after each use and again before being placed in use.

(2) Floors and work tables shall be kept clean.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.540 Spray process drying facilities.

(a) Driers shall be of a continuous discharge type and so constructed and equipped to prevent an excess accumulation of powder in the drier, bags, and powder conveyors.

(b) Driers shall be of approved construction and materials, with welded seams, and the surfaces shall be smooth to allow for thorough cleaning.

(c) Driers shall be equipped with approved air intake filters.

(d) Air shall be drawn into the drier from sources free from foul odors, dust, and dirt.

(e) Indirect heat or the use of an approved premixing device or other approved devices for securing complete combustion in direct-fired units is required. A premix-type burner, if used, shall be equipped with approved air filters at blower intake.

(f) High-pressure pump heads and lines shall be of stainless steel construction or equivalent which will allow for thorough cleaning.

(g) Preheating units, if used, shall be of stainless steel construction, or equivalent which will allow thorough cleaning.

(h) Powder conveying equipment shall be so constructed as will facilitate thorough cleaning.

(i) Sifters shall be constructed of an approved metal or metal lined interior. The sifting screens and frames shall be of an approved metal construction. Sifters shall be so constructed that accumulations of large particles or lumps of dried eggs can be removed continuously while the sifters are in operation.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.542 Spray process drying operations.

(a) The drying room shall be kept in a clean condition and free of flies, insects, and rodents.

(b) Low-pressure lines, high-pressure lines, high- and low-pressure pumps, homogenizers, and pasteurizers shall be cleaned by acceptable inplace cleaning methods or dismantled and cleaned after use or as necessary when operations have been interrupted.

(1) Spray nozzles, orifices, cores, or whizzers shall be cleaned immediately after cessation of drying operations.

(2) Equipment shall be sanitized within 2 hours prior to resuming operations.

(c) Drying units, conveyors, sifters, and packaging systems shall be cleaned whenever wet powder is encountered or when other conditions occur which would adversely affect the product. The complete drying unit, including sifters, conveyors, and powder coolers shall be either wet washed or dry cleaned. A combination of wet washing and dry cleaning of the complete drying unit shall not be permitted unless that segment of the unit to be cleaned in a different manner is completely detached or disconnected from the balance of the drying unit.

(1) Sifters and conveyors used for other than dried albumen shall be cleared of powder when such equipment is not to be used for a period of 24 hours or longer.

(2) Collector bags shall be cleaned as often as needed to maintain them in an acceptable clean condition.

(d) Powder shall be sifted and the screen shall be replaced whenever torn or worn.

(e) Accumulations of large particles or lumps of dried eggs shall be removed from the sifter screens continuously.

(f) All openings into the drier around ports, augers, high-pressure lines, etc., shall be closed to the extent possible during the drying operation to prevent entrance of nonfiltered air.

(g) Openings into the drying unit shall be closed when the drier is not in use, except when the drying unit has been completely emptied of powder and wet washed. This includes, but is not limited to, openings, for the air intake and exhaust systems, nozzle openings, ports, augers, etc.

§ 590.544 Spray process powder; definitions and requirements.

(a) Definition of product:

(1) *Primary powder* is that powder which is continuously removed from the primary or main drying chamber while the drying unit is in operation.

(2) *Secondary powder* is that powder which is continuously and automatically removed from the secondary chamber and/or bag collector chamber while the drying unit is in operation.

(3) *Sweep-down powder* is that powder which is recovered in the brush-down process from the primary or secondary chamber and conveyors.

(4) *Brush bag powder* is that powder which is brushed from the collector bags.

(b) Secondary powder shall be continuously discharged and mixed with

the primary powder by methods approved by the Administrator.

(c) Edible dried egg products, including edible ingredients which may be added to such dried products, may be dry-blended: *Provided*, That the blending is done in a room as provided in § 590.548 or in a closed blending system and in accordance with clean, sanitary practices and such procedures as may be prescribed by the Administrator.

(d) Any edible dried egg powder may be reconstituted, repasteurized, and redried when accomplished in a clean, sanitary manner and in accordance with such procedures as may be prescribed by the Administrator.

(e) Edible dried egg powder obtained from the sweep down, screenings, brush bag (except for brush bag powder from albumen driers), and improperly dried or scorched powder shall be reconstituted, repasteurized, and redried.

(f) Approximately the first and last 175 pounds of powder from the main driers for each continuous operation shall be checked for improperly dried or scorched powder.

§ 590.546 Albumen flake process drying facilities.

(a) Drying facilities shall be constructed in such a manner as will allow thorough cleaning and be equipped with approved intake filters.

(b) The intake air source shall be free from foul odors, dust, and dirt.

(c) Premix-type burners, if used, shall be equipped with approved air filters at blower intake.

(d) Fermentation tanks, drying pans, trays or belts, scrapers, curing racks, and equipment used for pulverizing pan dried albumen shall be constructed of approved materials in such a manner as will permit thorough cleaning.

(e) Sifting screens shall be constructed of approved materials in such a manner as will permit thorough cleaning and be in accordance with the specification for the type of albumen produced.

§ 590.547 Albumen flake process drying operations.

(a) The fermentation, drying, and curing rooms shall be kept in a dust-free clean condition and free of flies, insects, and rodents.

(b) Drying units, racks, and trucks shall be kept in a clean and sanitary condition.

(c) Drying pans, trays, belts, scrapers, or curing racks, if used, shall be kept in a clean condition.

(d) Oils and waxes used in oiling drying pans or trays shall be of edible quality.

(e) Equipment used for pulverizing or sifting dried albumen shall be kept in a clean condition.

§ 590.548 Drying, blending, packaging, and heat treatment rooms and facilities.

(a) *General.* Processing rooms shall be maintained in a clean condition and free of flies, insects, and rodents. The drying, blending, and packaging rooms shall be well-lighted and have ceilings and walls of a tile surface, enamel paint, or other water-resistant material.

(1) The floors shall be free from cracks or rough surfaces where water or dirt could accumulate.

(2) The intersections of the walls and floors shall be impervious to water and the floor shall be sloped for adequate drainage.

(3) Metal storage racks or cabinets shall be provided for storing of tools and accessories.

(b) Dry blending of edible egg products, including adding edible dry ingredients, and/or packaging of spray-dried products shall be done in a room separate from other processing operations. Dry blending may also be done in other areas: *Provided*, That it is accomplished in an approved closed blending system.

(1) Blending and packaging rooms for pasteurized products shall be provided with an adequate positive flow of approved outside filtered air.

(2) Blending and packaging equipment and accessories which come into contact with the dried product shall be of an approved construction without open seams and of materials that can be kept clean and which will have no deleterious effect on the product. Service tables shall be of approved metal construction without open seams and surfaces shall be smooth to permit thorough cleaning.

(3) Package liners shall be inserted in a sanitary manner, and equipment and

supplies used in the operation shall be kept off the floor.

(4) Utensils used in packaging dried eggs shall be kept clean at all times and whenever contaminated shall be cleaned and sanitized. When not in use, scoops, brushes, tampers, and other similar equipment shall be stored in sanitary cabinets or racks provided for this purpose.

(5) Automatic container fillers shall be of a type that will accurately fill given quantities of product into the containers. Scales shall be provided to accurately check the weight of the filled containers. All equipment used in mechanically packaging dried egg products shall be vacuum cleaned daily.

(c) The heat treatment room shall be of an approved construction and be maintained in a clean condition. The room or rooms shall be of sufficient size so that product to be heat treated can be so spaced to assure adequate heat and air circulation. The room shall have an adequate heat supply and a continuous air circulation system.

§ 590.549 Dried egg storage.

Dried egg storage shall be sufficient to adequately handle the production of the plant and shall be kept clean, dry, and free from objectionable odors.

§ 590.550 Washing and sanitizing room or area facilities.

(a) This room or area shall be well lighted, and of sufficient size to permit operators to properly wash and sanitize all equipment at the rate required by the size of the operation. Adequate exhaust shall be provided to assure the prompt removal of odors and vapors and the air flow shall be away from the breaking room. If the washing and sanitizing is not done in a separate room, it shall be in an area well segregated from the breaking areas and be well ventilated with air movement directed away from the breaking operations so that odors and vapors do not permeate the breaking areas.

(b) Ceiling and walls shall have a surface of tile, enamel paint, or other water-resistant material.

(c) Floors shall be adequately sloped for proper drainage, be free from cracks or rough surfaces where water and dirt could accumulate and the intersections with walls shall be impervious to water.

§ 590.552 Cleaning and sanitizing requirements.

(a) *Cleaning.* (1) Equipment used in egg processing operations which comes in contact with liquid eggs or exposed edible products shall be cleaned to eliminate organic matter and inorganic residues. This may be accomplished by any sanitary means but it is preferable (unless high pressure cleaning is used) to flush soiled equipment with clean cool water, dismantle it when possible, wash by brushing with warm water containing a detergent and followed by rinsing with water. It is essential to have the equipment surfaces thoroughly clean if effective sanitizing is to be attained.

(2) Equipment shall be cleaned with such frequency as is specified elsewhere under the sanitary requirements for the particular kind of operation and type of equipment involved.

(3) C.I.P. (cleaned-in-place) shall be considered to be acceptable only if the methods and procedures used accomplish cleaning equivalent to that obtained by thorough manual washing and sanitizing of dismantled equipment. The Administrator shall determine the acceptability of C.I.P. cleaning procedures and may require bacteriological tests and periodic dismantling of equipment as a basis for such determination.

(b) *Sanitizing.* (1) Sanitizing shall be accomplished by such methods as approved by the Administrator.

(i) Chemicals and compounds used for sanitizing shall have approval by the Administrator prior to use.

(ii) Sanitizing by use of hypochlorites or other approved sanitizing solutions shall be accomplished by subjecting the equipment surfaces to such sanitizing solution containing a maximum strength of 200 p.p.m. of available chlorine or its equivalent. These solutions shall be changed whenever the strength drops to 100 p.p.m. or less of available chlorine or its equivalent.

(2) Shell eggs which have been sanitized and equipment which comes in contact with edible products shall be rinsed with clean water after sanitizing

if other than hypochlorites are used as sanitizing agents unless otherwise approved by the Administrator.

§ 590.560 Health and hygiene of personnel.

(a) Personnel facilities, including toilets, lavatories, lockers, and dressing rooms shall be adequate and meet State and local requirements for food processing plants.

(b) Toilets and dressing rooms shall be kept clean and adequately ventilated to eliminate odors and kept adequately supplied with soap, towels, and tissues. Toilet rooms shall be ventilated to the outside of the building.

(c) No person affected with any communicable disease in a transmissible stage or a carrier of such disease, or with boils, sores, infected wounds, or wearing cloth bandages on hands shall be permitted to come in contact with eggs in any form or with equipment used to process such eggs.

(d) Workers coming into contact with liquid or dried eggs, containers, or equipment shall wear clean outer uniforms.

(e) Plant personnel handling exposed edible product shall wash their hands before beginning work, and upon returning to work after leaving the work room.

(f) Expectorating, or other unsanitary practices, shall not be permitted.

(g) Use of tobacco in any form or the wearing of jewelry, nail polish, or perfumes shall not be permitted in any area where edible products are exposed.

(h) Hair nets or caps shall be properly worn by all persons in breaking and packaging rooms.

§ 590.570 Pasteurization of liquid eggs.

(a) Pasteurization facilities: The facilities for pasteurization of egg products shall be adequate and of approved construction so that all products will be processed as provided for in this section. Pasteurization equipment for liquid egg product shall include a holding tube, an automatic flow diversion valve, thermal controls, and recording devices to determine compliance for pasteurization as set forth in paragraph (b) of this section. The temperature of the heated liquid egg product shall be continuously and automatically recorded during the process.

(b) Pasteurizing operations: Every particle of all products must be rapidly heated to the required temperature and held at that temperature for the required minimum holding time as set forth in this section. The temperatures and holding times listed in Table I of this section are minimum. The product may be heated to higher temperatures and held for longer periods of time. Pasteurization procedures shall assure complete pasteurization, and holding, packaging, facilities and operations shall be such as to prevent contamination of the product.

TABLE I—PASTEURIZATION REQUIREMENTS [1]

Liquid egg product	Minimum temperature requirements (°F.)	Minimum holding time requirements (*Minutes*)
Albumen (without use of chemicals)	134	3.5
	132	6.2
Whole egg	140	3.5
Whole egg blends (less than 2 percent added nonegg ingredients)	142	3.5
	140	6.2
Fortified whole egg and blends (24–38 percent egg solids, 2–12 percent added nonegg ingredients)	144	3.5
	142	6.2
Salt whole egg (with 2 percent or more salt added)	146	3.5
	144	6.2
Sugar whole egg (2–12 percent sugar added)	142	3.5
	140	6.2
Plain yolk	142	3.5
	140	6.2
Sugar yolk (2 percent or more sugar added)	146	3.5
	144	6.2
Salt yolk (2–12 percent salt added)	146	3.5
	144	6.2

[1] Pasteurization of egg products not listed in this table shall be in accordance with paragraph (c) of this section.

(c) Other methods of pasteurization may be approved by the Administrator when such treatments give equivalent effects to those specified in paragraph (b) of this section for those products or other products and results in a salmonella negative product.

§ 590.575 Heat treatment of dried whites.

Heat treatment of dried whites is an approved method for pasteurization and the product shall be heated throughout for such times and at such

temperatures as will result in salmonella negative product.

(a) The product to be heat treated shall be held in the heat treatment room in closed containers and shall be spaced to assure adequate heat penetration and air circulation. Each container shall be identified as to type of product (spray or pan dried) and with the lot number or production code number.

(b) The minimum requirements for heat treatment of spray or pan dried albumen shall be as follows:

(1) Spray dried albumen shall be heated throughout to a temperature not less than 130 °F and held continuously at such temperature not less than 7 days and until it is salmonella negative.

(2) Pan dried albumen shall be heated throughout to a temperature of not less than 125 °F and held continuously at such temperature not less than 5 days and until it is salmonella negative.

(3) Methods of heat treatment of spray dried or pan dried albumen, other than listed in paragraphs (b) (1) and (2) of this section, may be approved by the Administrator upon receipt of satisfactory evidence that such methods will result in salmonella negative products.

(c) Dried whites which have been heat treated in the dried form shall be sampled and analyzed for the presence of Salmonellae as required in § 590.580.

(d) Records shall be maintained for 1 year of the following:

(1) Types of product;

(2) Lot number;

(3) Heat treatment room temperatures;

(4) Product temperatures;

(5) Length of time product is held in heat treatment room;

(6) Results of all laboratory analyses made for the presence of Salmonellae.

(e) Dried whites processed and tested in accordance with all of the applicable requirements specified in this section may be labeled ''Pasteurized.''

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49169, Sept. 21, 1995; 60 FR 58199, Nov. 27, 1995]

LABORATORY

§ 590.580 Laboratory tests and analyses.

The official plant, at their expense, shall make tests and analyses to determine compliance with the Act and the regulations.

(a) Samples shall be drawn from liquid, frozen or dried egg products and analyzed for compliance with the standards of identity (if any) and with the product label.

(b) To assure adequate pasteurization, pasteurized egg products and heat treated dried egg whites shall be sampled and analyzed for the presence of Salmonellae in accordance with such sequence, frequency, and approved laboratory methods as prescribed by the AMS Science Division Director. The samples of pasteurized egg products and heat treated dried egg whites shall be drawn from the final packaged form.

(c) Results of all analyses and tests performed under paragraphs (a) and (b) of this section shall be provided to the inspector promptly upon receipt by the plant. If samples of pasteurized products or heat treated dried egg whites, in addition to those described in paragraphs (a) and (b) of this section, are analyzed for the presence of Salmonella, the plant shall immediately advise the inspector of any such samples which are determined to be Salmonella positive.

(d) USDA will draw confirmation samples and submit them to a AMS Science Division laboratory at USDA's expense to determine the adequacy of the plant's tests and analyses.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 58 FR 42413, Aug. 9, 1993; 60 FR 49170, Sept. 21, 1995; 60 FR 58199, Nov. 27, 1995]

EXEMPTED EGG PRODUCTS PLANTS

§ 590.600 Application for exemption.

An application for exemption from the continuous inspection requirements must be made in writing on

forms approved by the Administrator and filed with the inspection service.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982]

§ 590.610 Criteria for exemption.

Any plant processing egg products may qualify for exemption where:

(a) The facility, operating procedures and practices, and sanitation meet the standards required for official egg products plants as are contained in §§ 590.500 through 590.580, and such exempted plants shall thereafter be subject to other provisions applicable to official plants which shall include maintaining records such as pasteurization temperatures and holding times, laboratory records, egg products testing procedures, and making all such records available for review.

(b) The eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards for U.S. Consumer Grade B shell eggs.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982]

§ 590.620 Authority of applicant.

Proof of authority of any person applying for exemption from continuous inspection may be required by the Administrator.

§ 590.630 Filing of application.

An application for exemption shall be regarded as filed only when it has been filled in completely and signed by the applicant and has been received in the office of the inspection service.

§ 590.640 Application for exemption; approval.

Any person desiring to process egg products pursuant to the exemption provision of the Act and these regulations must receive approval of such plant, facilities, and operating procedures as an exempted plant. An application for exemption shall be according to the following:

(a) *Initial survey*. When an application for exemption of a plant has been filed, a Supervisory Egg Products Inspector will make a survey and inspection of the premises and plant to determine if the facilities, methods of operation, and eggs received or used therein are suitable and adequate in accordance with:

(1) Section 590.610; and

(2) Such other administrative instructions as may be issued, from time to time, by the Service and which are in effect at the time of the aforesaid survey and inspection.

(b) *Final survey and exemption approval.* Upon notification by the applicant for exemption that all the criteria for exemption required in § 590.610 are in effect and an initial survey has been performed, the applicant shall:

(1) Submit drawings and specifications in accordance with the same requirements as official plants as specified in § 590.146(b);

(2) Submit labels for approval as specified in § 590.680;

(3) Request a final survey be made by a Supervisory Egg Products Inspector to determine if the plant is constructed and the facilities are installed in accordance with the approved drawings and these regulations.

(c) The plant will be approved for exemption only when all the requirements of this section have been met.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.650 Exempted plant registration number.

Each plant processing egg products which receives the Administrator's approval for exemption shall be assigned an ''Exempted Registration Number'' at the time the exemption approval is provided.

§ 590.660 Inspection of exempted plants.

Duly authorized representatives of the Administrator shall make such periodic inspections of exempted plants and records thereof as the Administrator may require to ascertain if any of the provisions of the Act or these regulations applicable to exempted plants have been violated. Such representatives shall be afforded access, at any reasonable time, to any plant or

place of business subject to inspection under the provisions of the Act.

§ 590.670 Termination of exemption.

The Administrator may suspend or terminate any exemption if the criteria for exemption required in § 590.610 are not being met. In addition, if any violation has been committed, the applicable penalties provided in this part may be enforced as provided in the Act.

§ 590.680 Approval of labeling for egg products processed in exempted egg products processing plants.

(a) The labels for egg products which are capable for use as human food shall be submitted to the Administrator for approval. The submission and approval shall be the same as for official plants as required in § 590.411 except the labels or containers shall not bear official identification.

(b) The label or container shall legibly and conspicuously bear the statement: ''Exempted—E.P.I.A. Registration No. _____.'' The registration number shall be that assigned to the exempted plant as provided in § 590.650.

IDENTIFICATION OF RESTRICTED EGGS OR EGG PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

§ 590.800 Identification of restricted eggs.

The shipping container of restricted eggs shall be determined to be satisfactorily identified if such container bears the packer's name and address, the quality of the eggs in the container (e.g., dirties, checks, inedibles, or loss), or the statement ''Restricted Eggs—For Processing Only In An Official USDA Egg Products Plant,'' for checks or dirties, or ''Restricted Eggs—Not To Be Used As Human Food,'' for inedibles, loss, and incubator rejects, or ''Restricted Eggs—To Be Regraded'' for graded eggs which contain more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. The size of the letters of the identification wording shall be as required in § 590.860.

[40 FR 20060, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§ 590.840 Identification of inedible, unwholesome, or adulterated egg products.

All inedible, unwholesome, or adulterated egg products shall be identified with the name and address of the processor, the words ''Inedible Egg Products—Not To Be Used as Human Food.''

§ 590.860 Identification wording.

The letters of the identification wording shall be legible and conspicuous.

[37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

IMPORTS

§ 590.900 Requirements for importation of egg products or restricted eggs into the United States.

(a) Egg products and restricted eggs may be imported into the United States from any foreign country only in accordance with these regulations. The term *United States* means any State of the United States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and the District of Columbia. The importation of any egg or egg product in violation of the regulations of this part is prohibited.

(b) All such imported articles shall upon entry into the United States be deemed and treated as domestic articles and be subject to the other provisions of the Act, these regulations, and other Federal or State requirements.

§ 590.905 Importation of restricted eggs or eggs containing more restricted eggs than permitted in the official standards for U.S. Consumer Grade B.

No containers of restricted egg(s) other than checks or dirties shall be imported into the United States. The shipping containers of such eggs shall be identified with the name, address, and country of origin of the exporter,

and the date of pack and quality of the eggs (e.g., checks, or dirties) preceded by the word ''Imported'' or the statement ''Imported Restricted Eggs—For Processing Only In An Official USDA Plant,'' or ''Restricted Eggs—Not To Be Used As Human Food.'' Such identification shall be legible and conspicuous. Alternatively, for properly sealed and certified shipments of shell eggs imported for breaking at an official egg products plant, the shipping containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§ 590.910 Eligibility of foreign countries for importation of egg products into the United States.

(a) Whenever it is determined by the Administrator that the system of egg products inspection maintained by any foreign country is such that the egg products produced in such country are processed, labeled, and packaged in accordance with, and otherwise comply with, the standards of the Act and these regulations including, but not limited to the same sanitary, processing, facility requirements, and continuous Government inspection as required in §§ 590.500 through 590.580 applicable to inspected articles produced within the United States, notice of that fact will be given by listing the name of such foreign country in paragraph (b) of this section. Thereafter, egg products from the countries so listed shall be eligible, subject to the provisions of this part and other applicable laws and regulations, for importation into the United States. Such products to be imported into the United States from these foreign countries must meet, to the extent applicable, the same standards and requirements that apply to comparable domestic products as set forth in these regulations. Egg products from foreign countries not listed herein are not eligible for importation into the United States, except as provided by § 590.960. In determining if the inspection system of a foreign country is the equivalent of the system maintained by the United States, the Administrator shall review the inspection regulations of the foreign country and make a survey to determine the manner in which the inspection system is administered within the foreign country. The survey of the foreign inspection system may be expedited by payment by the interested Government agency in the foreign country of the travel expenses incurred in making the survey. After approval of the inspection system of a foreign country, the Administrator may, as often and to the extent deemed necessary, authorize representatives of the Department to review the system to determine that it is maintained in such a manner as to be the equivalent of the system maintained by the United States.

(b) It has been determined that each of the following foreign countries maintain an egg products inspection system that is the equivalent of the system maintained by the United States: Canada, The Netherlands.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 42 FR 48327, Sept. 23, 1977. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 52 FR 42426, Nov. 5, 1987]

§ 590.915 Foreign inspection certificate requirements.

(a) Except as provided in § 590.960, each consignment imported into the United States must have an electronic foreign inspection certification or a paper foreign inspection certificate issued by an official of the foreign government agency responsible for the inspection and certification of the product.

(b) An official of the foreign government agency must certify that any product described on any official certificate was produced in accordance with the regulatory requirements § 590.910.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; and bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue the inspection certificates for products imported into the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification mark on the units;

(8) The net weight of each lot; and

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

[79 FR 56235, Sept. 19, 2014]

§ 590.920 Import inspection application.

(a) Applicants must submit an import inspection application to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted (electronically or on paper) to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 590.960 and 590.965.

[79 FR 56235, Sept. 19, 2014]

§ 590.925 Inspection of imported egg products.

(a) Except as provided in § 590.960, egg products offered for importation from any foreign country shall be subject to inspection in accordance with established inspection procedures, including the examination of the labeling information on the containers, by an inspector before the product shall be admitted into the United States. Importers will be advised of the point where inspection will be made, and in case of small shipments (less than carload lots), the importer may be required to move the product to the location of the nearest inspector.

(b) Inspectors may take samples, without cost to the United States, of any product offered for importation which is subject to analysis or quality determination, except that samples shall not be taken of any products offered for importation under § 590.960, unless there is reason for suspecting the presence therein of a substance in violation of that section.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69972, Dec. 17, 1998]

§ 590.930 Imported egg products; retention in customs custody; delivery under bond; movement prior to inspection; sealing; handling; facilities, and assistance.

(a) No egg products required by this part to be inspected shall be released from customs custody prior to required inspections, but such product may be delivered to the consignee, or his agent, prior to inspection if the consignee shall furnish a bond, in the form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through customs.

(b) Notwithstanding paragraph (a) of this section, no product required by this part to be inspected shall be moved prior to inspection from the

port of arrival where first unloaded, and if arriving by water from the wharf where first unloaded at such port, to any place other than the place designated in accordance with this part as the place where the same shall be inspected; and no product shall be conveyed in any manner other than in compliance with this part.

(c) Means of conveyance or packages in which any product is moved in accordance with this part, prior to inspection, from the port or wharf where first unloaded in the United States, shall be sealed with special import seals of the U.S. Department of Agriculture or otherwise identified as provided herein, unless already sealed with customs or consular seals in accordance with the customs regulations. Such special seals shall be affixed by an inspector or, if there is no inspector at such port, by a customs officer. In lieu of sealing packages, the carrier or importer may furnish and attach to each package of product a warning notice on bright yellow paper, not less than 5 × 8 inches in size, containing the following legend in black type of a conspicuous size:

(Name of Truck Line or Carrier)

NOTICE

This package of _____ must be delivered intact to an inspector of the Poultry Division, U.S. Department of Agriculture.

WARNING

Failure to comply with these instructions will result in penalty action being taken against the holder of the customs entry bond.

If the product is found to be acceptable upon inspection, the product may be released to the consignee, or his agent, and this warning notice defaced.

(d) No person shall affix, break, alter, deface, mutilate, remove, or destroy any special import seal of the U.S. Department of Agriculture, except customs officers or inspectors, or as provided in paragraph (f) of this section.

(e) No product shall be removed from any means of conveyance or package sealed with a special import seal of the U.S. Department of Agriculture, except under the supervision of an inspector or a customs officer, or as provided in paragraph (f) of this section.

(f) In case of a wreck or similar extraordinary emergency, the special import seal of the U.S. Department of Agriculture on a car, truck, or other means of conveyance may be broken by the carrier and, if necessary, the articles may be reloaded into another means of conveyance for transportation to destination. In all such cases, the carrier shall immediately report the facts by telegraph to the Chief of the Grading Branch.

(g) The consignee or his agent shall provide such facilities and assistance as the inspector may require for the inspection and handling and marking of products offered for importation.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6660, Apr. 1, 1972; 40 FR 20060, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46070, Oct. 15, 1982; 47 FR 54421, Dec. 3, 1982; 63 FR 69972, Dec. 17, 1998]

§ 590.935 Means of conveyance and equipment used in handling egg products to be maintained in sanitary condition.

Compartments of boats, railroad cars, and other means of conveyance transporting any product to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling such product offered for importation, shall be maintained in a sanitary condition.

§ 590.940 Marking of egg products offered for importation.

Egg products which, upon inspection, are found to be acceptable for importation into the United States, and are properly labeled and bear the inspection mark of the country of origin, need no further identification.

[40 FR 20060, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995]

§ 590.945 Foreign egg products offered for importation; reporting of findings to customs; handling of products refused entry.

(a) Inspectors shall report their findings to the collector of customs at the port where products are offered for entry, and shall request the collector

to refuse entry to egg products which are marked or designated ''U.S. Refused Entry'' or otherwise are not in compliance with the regulations in this part. Unless such products are exported by the consignee within a time specified by the collector of customs (usually 30 days), the consignee shall cause the destruction of such products for human food purposes under the supervision of an inspector. If products are destroyed for human food purposes under the supervision of an inspector, he shall give prompt notice thereof to the District Director of Customs.

(b) Consignees shall, at their own expense, return immediately to the collector of customs, in means of conveyance or packages sealed by the U.S. Department of Agriculture, any egg products received by them under this part which in any respect do not comply with this part.

(c) Except as provided in §590.930(a), no person shall remove or cause to be removed from any place designated as the place of inspection, any egg products which the regulations require to be marked in any way, unless the same has been clearly and legibly marked in compliance with this part.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6660, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§ 590.950 Labeling of containers of eggs or egg products for importation.

(a) Immediate containers of product offered for importation shall bear a label, printed in English, showing:

(1) The name of product;

(2) the name of the country of origin of the product, and for consumer packaged products, preceded by the words ''Product of,'' which statement shall appear immediately under the name of the product;

(3) [Reserved]

(4) For shell eggs, the words, ''Keep Refrigerated,'' or words of similar meaning;

(5) for egg products, the word ''Ingredients'' followed by a list of the ingredients in order of descending proportions by weight;

(6) the name and place of business of manufacturer, packer, or distributor, qualified by a phrase which reveals the connection that such person has with the product;

(7) an accurate statement of the quantity;

(8) for egg products, the inspection mark of the country of origin; and

(9) The date of production and plant number of the plant at which the egg product was processed and/or packed.

(b) For properly sealed and certified shipments of shell eggs imported for breaking at an official egg products plant, the immediate containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.

(c) The labels shall not be false or misleading in any respect.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 45675, Aug. 27, 1998; 63 FR 69972, Dec. 17, 1998]

§ 590.955 Labeling of shipping containers of eggs or egg products for importation.

(a) Shipping containers of foreign product which are shipped to the United States shall bear in a prominent and legible manner:

(1) The common or usual name of the product;

(2) The name of the country of origin;

(3) The plant number of the plant in which the egg product was processed and/or packed;

(4) The inspection mark of the country of origin;

(5) [Reserved]

(6) For shell eggs, the words ''Keep refrigerated'' or words of similar meaning.

(b) Labeling on shipping containers examined at the time of inspection in the United States, if found to be false or misleading, shall be cause for the product to be refused entry.

(c) [Reserved]

(d) In the case of products which are not in compliance solely because of misbranding, such products may be brought into compliance with the regulations only under the supervision of

an authorized representative of the Administrator.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 45675, Aug. 27, 1998; 63 FR 69972, Dec. 17, 1998]

§ 590.956 Relabeling of imported egg products.

(a) Egg products eligible for importation may be relabeled with an approved label under the supervision of an inspector at an official egg products plant or other location. The new label for such product shall indicate the country of origin except for products which are reprocessed (repasteurized, or in the case of dried products, dry blended with products produced in the United States) in an official egg products plant.

(b) The label for relabeled products must state the name, address, and zip code of the distributor, qualified by an appropriate term such as ''packed for'', ''distributed by'' or ''distributors''.

[60 FR 49171, Sept. 21, 1995]

§ 590.960 Small importations for consignee's personal use, display, or laboratory analysis.

Any egg products which are offered for importation, exclusively for the consignee's personal use, display, or laboratory analysis, and not for sale or distribution; which is sound, healthful, wholesome, and fit for human food; and which is not adulterated and does not contain any substance not permitted by the Act or regulations, may be admitted into the United States without a foreign inspection certificate. Such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part: *Provided,* That the Department may, with respect to any specific importation, require that the consignee certify that such product is exclusively for the consignee's personal use, display, or laboratory analysis and not for sale or distribution. The amount of such product imported shall not exceed 30 pounds of liquid or frozen eggs, or 50 pounds of dried egg products, unless otherwise authorized by the Administrator.

[37 FR 6660, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69972, Dec. 17, 1998]

§ 590.965 Returned U.S. inspected and marked products; not importations.

Products which have been inspected by the United States Department of Agriculture and so marked, and which are returned from foreign countries are not importations within the meaning of this part. Such returned shipments shall be reported to the Administrator by letter.

§ 590.970 Charges for storage, cartage, and labor with respect to products imported contrary to the Act.

All charges for storage, cartage, and labor with respect to any product which is imported contrary to this part shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such product and any other product thereafter imported under the Act by or for such owner or consignee.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46071, Oct. 15, 1982; 47 FR 54421, Dec. 3, 1982]

PART 592—VOLUNTARY INSPECTION OF EGG PRODUCTS

Sec.

AUTHORITY: 7 U.S.C. 1621–1627.

SOURCE: 69 FR 1648, Jan. 12, 2004, unless otherwise noted.

DEFINITIONS

§ 592.1 Meaning of words.

Under the regulations in this part words in the singular shall be deemed to import the plural and vice versa, as the case may demand.

§ 592.2 Terms defined.

For the purpose of the regulations in this part, unless the context otherwise requires, the following terms shall be construed, respectively:

Act means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087; 7 U.S.C. 1621 *et seq.*), or any other Act of Congress conferring like authority.

Administrator means the Administrator of the Food Safety and Inspection Service (FSIS) of the Department or any other officer or employee of the Department to whom there has been delegated, or to whom there may be delegated the authority to act in the Administrator's stead.

Applicant means any interested party who requests any inspection service, or appeal inspection, with respect to any product.

Class means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind, species, or method of processing.

Condition means any condition (including, but not being limited to, the state of preservation, cleanliness, soundness, wholesomeness, or fitness for human food) of any product which affects its merchantability; or any condition, including, but not being limited to, the processing, or packaging which affects such product.

Department means the United States Department of Agriculture.

District Manager means the manager in charge of a district, which is a designated geographical area.

Eggs of Current Production means shell eggs that have moved through the usual marketing channels since the date of lay and are not in excess of 60 days old.

Holiday or Legal holiday means the legal public holidays specified by the

Congress in paragraph (a) of section 6103, Title 5, of the United States Code.

Inspection means the act by inspection program personnel of:

(1) Determining, according to these regulations, the class, quality, quantity, or condition of any product by examining each unit thereof or a representative sample drawn by inspection program personnel;

(2) Issuing a certificate; or

(3) Identifying, when requested by the applicant, any product by means of official identification pursuant to the Act and this part.

Inspection certificate or *certificate* means a statement, either written or printed, issued by inspection program personnel pursuant to the Act and this part, relative to the class, quality, quantity, and condition of products.

Inspection program personnel (employee) means employees of the Department authorized by the Secretary to investigate and certify, in accordance with the Act and this part, to shippers of products and other interested parties the class, quality, quantity, and condition of such products.

Interested party means any person financially interested in a transaction involving any inspection or appeal inspection of any product.

Official plant means any plant in which the facilities and methods of operation therein have been found by the Administrator to be suitable and adequate for inspection in accordance with this part and in which such service is carried on.

Person means any individual, partnership, association, business trust, corporation, or any organized group of persons, whether incorporated or not.

Product or *products* means eggs (whether liquid, frozen, or dried), egg products, and any food product that is prepared or manufactured and contains eggs as an ingredient.

Program employee means any person employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the program.

Quality means the inherent properties of any product that determine its relative degree of excellence.

Regulations mean the provisions in this part.

Sampling means the act of taking samples of any product for inspection.

Secretary means the Secretary of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated, the authority to act in the Secretary's stead.

Service means: (1) Any inspection, in accordance with the Agriculture Marketing Act and the regulations in this part, of any product,

(2) Supervision, in any official plant, of the processing, packaging and identification, or

(3) Any appeal inspection of any previously inspected product.

Shell eggs mean the shell eggs of the domesticated chicken, turkey, duck, goose, and guinea.

§ 592.5 Designation of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended by Public Law 272, 84th Congress, provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications, and devices for making such marks or identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed below shall have the respective meanings specified:

(a) *Official certificate* means any form of certification, either written or printed, used under this part to certify with respect to the sampling, inspection, class, quality, quantity, or condition of products (including the compliance of products with applicable specifications).

(b) *Official memorandum* means any initial record of findings made by an authorized person in the process of inspecting, or sampling pursuant to this part, any processing or plant-operation report made by an authorized person in

connection with inspecting, or sampling under this part and any report made by an authorized person of services performed pursuant to this part.

(c) *Official mark* means the inspection mark, and any other mark or symbol formulated pursuant to the regulations in this part, stating that the product was inspected, or for the purpose of maintaining the identity of the product.

(d) *Official identification* means any United States (U.S.) standard designation of class, quality, quantity, or condition specified in this part or any symbol, stamp, label, or seal indicating that the product has been officially inspected or indicating the class, quality, quantity, or condition of the product approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product.

(e) *Official device* means a printed label, or other method as approved by the Secretary for the purpose of applying any official mark or other identification to any product of the packaging material thereof.

ADMINISTRATION

§ 592.10 Authority.

The Administrator shall perform, for and under the supervision of the Secretary, such duties as the Secretary may require in the enforcement or administration of the provisions of the Act and this part. The Administrator is authorized to waive for a limited period any particular provisions of the regulations in this part to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements and at the same time to determine full compliance with the spirit and intent of the regulations in this part. The Food Safety Inspection Service and its officers and employees shall not be liable in damages through acts of commission or omission in the administration of this part.

GENERAL

§ 592.20 Kinds of services available.

The regulations in this part provide for the following kinds of services:

(a) Inspection of the processing in official plants of products containing eggs;

(b) Sampling of products; and

(c) Quantity and condition inspection of products.

(d) *Export certification.* Upon application, by any person intending to export any egg product, inspectors may make certifications regarding products for human food purposes, to be exported, as meeting conditions or standards that are not imposed or are in addition to those imposed by the regulations in the part and the laws under which such regulations were issued.

[69 FR 1648, Jan. 12, 2004, as amended at 81 FR 42235, June 29, 2016]

§ 592.22 Where service is offered.

Any product may be inspected wherever inspection program personnel are available and the facilities and the conditions are satisfactory for the conduct of the service.

§ 592.24 Basis of service.

(a) Products shall be inspected in accordance with such standards, methods, and instructions as may be issued or approved by the Administrator. All service shall be subject to supervision at all times by the applicable FSIS designated supervisor. Whenever the supervisor of an inspection program person has evidence that such inspection program employee incorrectly inspected a product, such supervisor shall take such action as is necessary to correct the inspection and to cause any improper official identification that appears on the product or containers thereof to be corrected prior to shipment of the product from the place of the initial inspection.

(b) Whenever service is performed on a sample basis, such sample shall be drawn in accordance with the instructions as issued by the Administrator.

PERFORMANCE OF SERVICES

§ 592.70 Identification.

All inspection program personnel and supervisors shall have in their possession at all times while on duty and present upon request the means of identification furnished by the Department to such person.

§ 592.80 Political activity.

All inspection program personnel are forbidden during the period of their respective appointments, to take an active part in political management or in political campaigns. Political activity in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate is prohibited, except as authorized by law or regulation of the Department. This applies to all appointees, including, but not being limited to, temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of this section will constitute grounds for dismissal.

§ 592.90 Authority and duties of inspection program personnel performing service.

(a) Inspection program personnel are authorized:

(1) To make such observations and inspections as they deem necessary to enable them to certify that products have been prepared, processed, stored, and otherwise handled in conformity with the regulations in this part;

(2) To supervise the marking of packages containing products that are eligible to be identified with official identification;

(3) To retain in their custody, or under their supervision, labels with official identification, marking devices, samples, certificates, seals, and reports of inspection program personnel;

(4) To deface or remove, or cause to be defaced or removed under their personal supervision, any official identification from any package containing products whenever the program employee determines that such products were not processed in accordance with the regulations in this part or are not fit for human food;

(5) To issue a certificate upon request on any product processed in the official plant; and

(6) To use retention tags or other devices and methods as may be approved by the Administrator for the identification and control of products that are not in compliance with the regulations in this part or are held for further examination, and any equipment, utensils, rooms or compartments that are found to be unclean or otherwise in violation of any of the regulations in this part. No product, equipment, utensil, room, or compartment shall be released for use until it has been made acceptable. Such identification shall not be removed by anyone other than inspection program personnel.

(b) Inspection program personnel shall prepare such reports and records as may be prescribed by the Administrator.

§ 592.95 Facilities and equipment to be furnished for use of inspection program personnel in performing service.

(a) Facilities and equipment for proper sampling, weighing, examination of products, and monitoring processing procedures shall be furnished by the official plant for use by inspection program personnel. Such facilities and equipment shall include but not be limited to a room or area suitable for sampling product and stationary or adequately secured storage box or cage (capable of being locked only by inspection program personnel) for holding official samples.

(b) Acceptable furnished office space and equipment, including but not being limited to, a desk, lockers or cabinets (equipped with a satisfactory locking device) suitable for the protection and storage of supplies, and with facilities for inspection program personnel to change clothing.

§ 592.96 Schedule of operation of official plants.

Inspection operating schedules for services performed pursuant to this part shall be requested in writing and approved by the appropriate District Office. Normal operating schedules for a full-week consist of a continuous 8-hour period per day (excluding but not to exceed 1 hour for lunch), 5 consecutive days per week, within the administrative workweek, Sunday through Saturday, for each shift required. Less than 8-hour schedules may be requested and will be approved if inspection program personnel are available. Clock hours of daily operations need not be specified in the request, although as a condition of continued approval, the hours of operation shall consist of a continuous 10-hour period

per day (excluding but not to exceed 1 hour for lunch), 4 consecutive days per week, within the administrative workweek, Sunday through Saturday for each full shift required. Inspection program personnel are to be given reasonable advance notice by management of any change in the hours the inspection service is requested.

APPLICATION FOR SERVICE

§ 592.100 Who may obtain service.

(a) An application for service may be made by any interested person, including, but not being limited to, the United States, any State, county, municipality, or common carrier, and any authorized agent of the foregoing.

(b) Where service is offered: Any product may be inspected, wherever an inspection program employee is available and the facilities and the conditions are satisfactory for the conduct of the service.

(c) The applicant must have a tax identification number for billing purposes.

§ 592.120 Authority of applicant.

Proof of the authority of any person applying for any service may be required at the discretion of the Administrator.

§ 592.130 How application for service may be made.

(a) On a fee basis. An application for service may be made with any inspection program personnel at or nearest the place where the service is desired. Such application for service may be made orally (in person or by telephone), in writing or by transmission. If an application for inspection service is made orally, the inspection program personnel with whom such application is made, or the Administrator, may require that the application be confirmed in writing.

(b) Form of application. Each application for inspection of a specified lot of any product shall include such information as may be required by the Administrator in regard to the product and the premises where such product is to be inspected.

§ 592.140 Application for inspection in official plants; approval.

Any person desiring to process products under inspection service must receive approval of such plant and facilities as an official plant prior to the installation of such service. The initial survey, drawings, and specifications to be submitted, changes and revisions in the official plant, and final survey and procedure for plant approval shall be in accordance with and conform to the applicable provisions of Part 590 of this chapter.

§ 592.150 When an application may be rejected.

(a) Any application for service may be rejected by the Administrator:

(1) Whenever the applicant fails to meet the requirements of the regulations in this part prescribing the conditions under which the service is made available;

(2) Whenever the product is owned by or located on the premises of a person currently denied the benefits of the Act;

(3) Where any individual holding office or a responsible position with or having a substantial financial interest or share in the applicant is currently denied the benefits of the Act or was responsible in whole or in part for the current denial of the benefits of the Act to any person;

(4) Where the Administrator determines that the application is an attempt on the part of a person currently denied the benefits of the Act to obtain service;

(5) Whenever the applicant, after an initial survey has been made in accordance with Part 590, fails to bring the plant, facilities, and operating procedures into compliance with the regulations in this part within a reasonable period of time;

(6) Notwithstanding any prior approval whenever, before inauguration of service, the applicant fails to fulfill commitments concerning the inauguration of the service;

(7) When it appears that to perform the services specified in this part would not be to the best interests of the public welfare or of the Government; or

(8) When it appears to the Administrator that prior commitments of the

Department necessitate rejection of the application.

(b) Each such applicant shall be promptly notified by registered mail of the reasons for the rejection. A written petition for reconsideration of such rejection may be filed by the applicant with the Administrator if postmarked or delivered within 10 days after receipt of notice of the rejection. Such petition shall state specifically the errors alleged to have been made by the Administrator in rejecting the application. Within 20 days following the receipt of such a petition for reconsideration, the Administrator shall approve the application or notify the applicant by registered mail of the reasons for the rejection thereof.

§ 592.160 When an application may be withdrawn.

An application for service may be withdrawn by the applicant at any time before the service is performed upon payment, by the applicant, of all expenses incurred by the Agency in connection with such application.

§ 592.170 Order of service.

Service shall be performed, insofar as practicable, in the order in which applications therefor are made except that precedence may be given to any application for an appeal.

§ 592.180 Suspension of plant approval.

(a) Any plant approval pursuant to the regulations in this part may be suspended for:

(1) Failure to maintain plant and equipment in a satisfactory state of repairs;

(2) The use of operating procedures that are not in accordance with the regulations in this part; or

(3) Alterations of buildings, facilities, or equipment that cannot be approved in accordance with the regulations in this part.

(b) During such period of suspension, inspection service shall not be rendered. However, the other provisions of the regulations in this part pertaining to providing service will remain in effect unless service is terminated in accordance with the terms thereof. If the plant facilities or methods of operation are not brought into compliance within a reasonable period of time to be specified by the Administrator, the application and service shall be terminated. Upon termination of service in an official plant pursuant to the regulations in this part, the plant approval shall also become terminated, and all labels, seals, tags, or packaging material bearing official identification shall, under the supervision of a person designated by the Administrator, either be destroyed, or if to be used at another location, modified in a manner acceptable to the Agency.

DENIAL OF SERVICE

§ 592.200 Debarment.

(a) The following acts or practices or the causing thereof may be deemed sufficient cause for the debarment by the Administrator of any person, including any agents, officers, subsidiaries, or affiliates of such person, from any or all benefits of the Act for a specified period.

(1) Misrepresentation, or deceptive or fraudulent act or practice. Any willful misrepresentation or any deceptive or fraudulent act or practice found to be made or committed by any person in connection with:

(i) The making or filing of an application for any service or appeal;

(ii) The making of the product accessible for sampling or inspection;

(iii) The making, issuing, or using, or attempting to issue or use, any certificate, symbol, stamp, label, seal, or identification authorized pursuant to the regulations in this part;

(iv) The use of the terms ''United States,'' ''U.S.,'' ''U.S. Inspected,'' ''Government Inspected,'' or terms of similar import in the labeling or advertising of any product;

(v) The use of any official stamp, symbol, label, seal, or identification in the labeling or advertising of any product.

(2) *Use of facsimile forms.* Using or attempting to use a form that simulates in whole or in part any certificate, symbol, stamp, label, seal, or identification authorized to be issued or used under the regulations in this part.

(3) Willful violation of the regulations. Any willful violation of the regulations in this part or of the Act.

(4) Interfering with inspection program personnel or program employee of the Agency. Any interference with or obstruction or any attempted interference or obstruction of or assault upon any inspection program personnel or program employee of the Agency in the performance of their duties. The giving or offering, directly or indirectly, of any money, loan, gift, or anything of value to a program employee of the Agency, or the making or offering of any contribution to or in any way supplementing the salary, compensation or expenses of a program employee of the Agency, or the offering or entering into a private contract or agreement with a program employee of the Agency for any services to be rendered while employed by the Agency.

(5) *Miscellaneous.* The existence of any of the conditions set forth in § 592.150 constituting the basis for the rejection of an application for inspection service.

§ 592.220 Other applicable regulations.

Compliance with the regulations in this part shall not excuse failure to comply with any other Federal or any State or municipal applicable laws or regulations.

§ 592.240 Report of violations.

Each inspection program employee shall report, in the manner prescribed by the Administrator, all violations and noncompliance under the Act and this part of which such inspection program employee has knowledge.

§ 592.260 Reuse of containers bearing official identification prohibited.

The reuse, by any person, of containers bearing official identification is prohibited unless such identification is applicable in all respects to product being packed therein. In such instances, the container and label may be used provided the packaging is accomplished under the supervision of inspection program personnel or program employee, and the container is in clean, sound condition and lined with a suitable inner liner.

IDENTIFYING AND MARKING PRODUCTS

§ 592.300 Approval of official identification.

Labeling procedures, required information on labels, and method of label approval, shall be in accordance with and conform to the applicable provisions of part 590 of this chapter.

§ 592.310 Form of official identification symbol and inspection mark.

(a) The shield set forth in Figure 1, containing the letters ''USDA,'' shall be the official identification symbol for the purposes of this part and when used, imitated, or simulated in any manner in connection with a product shall be deemed to constitute a representation that the product has been officially inspected for the purpose of § 592.5.

FIGURE 1.

(b) The inspection marks that are permitted to be used on products shall be contained within the outline of a shield and with the wording and design set forth in Figure 2 of this section, except the plant number may be followed by the letter ''G'' in lieu of the word ''plant.'' Alternatively, it may be omitted from the official shield if applied on the container's principal display panel or other prominent location and preceded by the word ''Plant'' or followed by the letter ''G.''

FIGURE 2.

§ 592.320 Products that may bear the inspection mark.

Products that are permitted to bear the inspection mark shall be processed in an official plant from edible shell eggs or other edible egg products eligible to bear the inspection mark and may contain other edible ingredients. The official mark, when used, shall be printed or lithographed and applied as a part of the principal display panel of the container, but shall not be applied to a detachable cover. v

§ 592.330 Unauthorized use or disposition of approved labels.

(a) Containers or labels that bear official identification approved for use pursuant to § 592.300 shall be used only for the purpose for which approved. Any unauthorized use or disposition of approved containers or labels that bear any official identification may result in cancellation of the approval and denial of the use of containers or labels bearing official identification or denial of the benefits of the Act pursuant to the provisions of § 592.200;

(b) The use of simulations or imitations of any official identification by any person is prohibited;

(c) Upon termination of inspection service in an official plant pursuant to the regulations in this part, all labels or packaging material bearing official identification to be used to identify product packed by the plant shall either be destroyed, or have the official identification completely obliterated under the supervision of a USDA representative, or, if to be used at another location, modified in a manner acceptable to the Agency.

§ 592.340 Supervision of marking and packaging.

(a) Evidence of label approval. Inspection program personnel shall authorize the use of official identification on any inspected product when they have evidence that such official identification or packaging material bearing such official identification has been approved in accordance with the provisions of § 592.300.

(b) Affixing of official identification. No official identification may be affixed to or placed on or caused to be affixed to or placed on any product or container thereof except by an inspection program employee or under the supervision of an inspection program employee or other person authorized by the Administrator. All such products shall have been inspected in accordance with the regulations in this part. Inspection program personnel shall have supervision over the use and handling of all material bearing any official identification.

(c) Labels for products sold under Government contract. Inspectors-in-charge may approve labels for containers of product sold under a contract specification to governmental agencies when such product is not offered for resale to the general public: Provided, that the contract specifications include complete specific requirements with respect to labeling, and are made available to inspection program personnel.

§ 592.350 Accessibility of product.

Each product for which service is requested shall be so placed as to disclose fully its class, quality, quantity, and condition as the circumstances may warrant.

§ 592.360 Certificates.

Certificates (including appeal certificates) shall be issued on forms approved by the Administrator.

§ 592.370 Certificate issuance.

When performing inspection service at locations other than an official establishment, inspection program peronnel shall issue a certificate covering each product inspected. An applicant may request issuance of a certificate for each production lot inspected.

§ 592.380 Disposition of certificates.

The original and a copy of each certificate issued pursuant to § 592.370, and not to exceed two additional copies thereof if requested by the applicant prior to issuance, shall, immediately upon issuance, be delivered or mailed to the applicant or designee. Other copies shall be filed and retained in accordance with the disposition schedule for inspection program records.

§ 592.390 Advance information.

Upon request of an applicant, all or part of the contents of any certificate issued to such applicant may be telephoned or transmitted to the applicant or designee, at the applicant's expense.

APPEALS

§ 592.400 Who may request an appeal inspection or review of an inspection program employee's decision.

An appeal inspection may be requested by any interested party who is dissatisfied with the determination by an inspection program employee of the class, quality, quantity, or condition of any product, as evidenced by the USDA inspection mark and accompanying label, or as stated on a certificate and a review may be requested by the operator of an official plant with respect to an inspection program personnel decision or on any other matter related to inspection in the official plant.

§ 592.410 Where to file an appeal.

(a) Appeal of inspection program personnel decision in an official plant. Any interested party who is not satisfied with the determination of the class, quality, quantity, or condition of product that was inspected by inspection program personnel in an official plant and has not left such plant, and the operator of any official plant who is not satisfied with a decision by inspection program personnel on any other matter relating to inspection in such plant, may request an appeal inspection or review of the decision by the inspection program employee by filing such request with the inspection program employee's immediate supervisor.

(b) All other appeal requests. Any interested party who is not satisfied with the determination of the class, quality, quantity, or condition of product that has left the official plant where it was inspected or inspected other than in an official plant may request an appeal inspection by filing such request with the District Manager in the district where the product is located.

§ 592.420 How to file an appeal.

The request for an appeal inspection or review of an inspection program employee's decision may be made orally or in writing. If made orally, written confirmation may be required. The applicant shall clearly state the identity of the product, the decision which is questioned, and the reasons for requesting the appeal service. If such appeal request is based on the results stated on an official certificate, the original and all copies of the certificate available at the appeal inspection site shall be provided to the appeal inspection program employee assigned to make the appeal inspection.

§ 592.430 When an application for an appeal inspection may be refused.

When it appears to the official with whom an appeal request is filed that the reasons given in the request are frivolous or not substantial, class, quality, quantity, or that the condition of the product has undergone a material change since the original inspection, or that the original lot has changed in some manner, or the Act or the regulations in this part have not been complied with, the applicant's request for the appeal inspection may be refused. In such case, the applicant shall be promptly notified of the reason(s) for refusal.

§ 592.440 Who shall perform the appeal.

(a) An appeal inspection or review of a decision requested under § 592.410(a)

shall be made by the inspection program employee's immediate supervisor or by an inspection program employee assigned by the immediate supervisor other than the inspection program employee whose inspection or decision is being appealed.

(b) Appeal inspections requested under § 592.410(b) shall be performed by an inspection program employee other than the inspection program employee who originally inspected the product.

(c) Whenever practical, an appeal inspection shall be conducted jointly by two inspection program employees. The assignment of the inspection program personnel who will make the appeal inspection under § 592.410(b) shall be made by the District Manager.

§ 592.450 Procedures for selecting appeal samples.

(a) *Prohibition on movement of product.* Products shall not have been moved from the place where the inspection being appealed was performed and must have been maintained under adequate refrigeration, when applicable.

(b) *Laboratory analyses.* The appeal sample shall consist of product taken from the original sample containers plus an equal number of containers selected at random. When the original sample containers cannot be located, the appeal sample shall consist of product taken at random from double the number of original sample containers.

(c) *Condition inspection.* The appeal sample shall consist of product taken from the original sample containers plus an equal number of containers selected at random. A condition appeal cannot be made unless all originally sampled containers are available.

§ 592.460 Appeal certificates.

Immediately after an appeal inspection is completed, an appeal certificate shall be issued to show that the original inspection was sustained or was not sustained. Such certificate shall supersede any previously issued certificate for the product involved and shall clearly identify the number and date of the superseded certificate. The issuance of the appeal certificate may be withheld until any previously issued certificate and all copies have been returned when such action is deemed necessary to protect the interest of the Government. When the appeal inspection program employee assigns a different class to the lot or determines that a net weight shortage exists, the lot shall be retained pending correction of the labeling or approval of the product disposition by the District Office.

FEES AND CHARGES

§ 592.500 Payment of fees and charges.

(a) Fees and charges for voluntary base time rate, overtime inspection service, holiday inspection service, and electronic export applications shall be paid by the interested party making the application for such service, in accordance with the applicable provisions of this section and § 592.510 through § 592.530, both inclusive. If so required by the inspection personnel, such fees and charges shall be paid in advance.

(b) Fees and charges for any service shall, unless otherwise required pursuant to paragraph (c) of this section, be paid by check, draft, or money order payable to the Food Safety Inspection Service and remitted promptly to FSIS.

(c) Fees and charges for any service under a cooperative agreement with any State or person shall be paid in accordance with the terms of such cooperative agreement.

(d) Exporters that submit electronic export certificate applications will be charged a fee per application submitted.

(e) For each calendar year, FSIS will calculate the electronic export certificate application fee, using the following formula: Labor Costs (Technical Support Cost + Export Library Maintenance Cost) + Information Technology Costs (On-going operations Cost + Maintenance Cost + eAuthentication Cost), divided by the number of export applications.

(f) FSIS will publish notice of the electronic export certificate application fee annually in the FEDERAL REGISTER.

[69 FR 1648, Jan. 12, 2004, as amended at 81 FR 42235, June 29, 2016]

§ 592.510 Basetime rate.

(a) For each calendar year, FSIS will calculate the basetime rate for inspection services, per hour per program employee, using the following formula: The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by the previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate.

(b) FSIS will calculate the benefits, travel and operating, overhead, and allowance for bad debt rate components of the basetime rate, using the following formulas:

(1) *Benefits rate.* The quotient of dividing the previous fiscal year's direct benefits costs by the previous fiscal year's total hours (regular, overtime, and holiday), plus the quotient multiplied by the calendar year's percentage cost of living increase. Some examples of direct benefits are health insurance, retirement, life insurance, and Thrift Savings Plan basic and matching contributions.

(2) *Travel and operating rate.* The quotient of dividing the previous fiscal year's total direct travel and operating costs by the previous fiscal year's total hours (regular, overtime, and holiday), plus the quotient multiplied by the calendar year's percentage of inflation.

(3) *Overhead rate.* The quotient of dividing the previous fiscal year's indirect costs plus the previous fiscal year's information technology (IT) costs in the Public Health Data Communication Infrastructure System Fund plus the previous fiscal year's Office of Management Program cost in the Reimbursable and Voluntary Funds plus the provision for the operating balance less any Greenbook costs (i.e., costs of USDA support services prorated to the service component for which fees are charged) that are not related to food inspection, by the previous fiscal year's total hours (regular, overtime, and holiday) worked across all funds, plus the quotient multiplied by the calendar year's percentage of inflation.

(4) *Allowance for bad debt rate.* Previous fiscal year's allowance for bad debt (for example, debt owed that is not paid in full by plants and establishments that declare bankruptcy) divided by the previous fiscal year's total hours (regular, overtime, and holiday) worked.

(c) The calendar year's cost of living increases and percentage of inflation factors used in the formulas in this section are based on the Office of Management and Budget's Presidential Economic Assumptions.

[76 FR 20228, Apr. 12, 2011]

§ 592.520 Overtime rate.

When operations in an official plant require the services of inspection personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime work. The official plant must give reasonable advance notice to the inspector of any overtime service necessary. For each calendar year, FSIS will calculate the overtime rate for inspection service, per hour per program employee, using the following formula: The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase multiplied by 1.5, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate. FSIS calculates the benefits rate, the travel and operating rate, the overhead rate, and the allowance for bad debt using the formulas set forth in § 592.510(b), and the cost of living increases and percentage of inflation factors set forth in § 592.510(c).

[71 FR 2143, Jan. 13, 2006, as amended at 76 FR 20228, Apr. 12, 2011]

§ 592.530 Holiday rate.

When an official plant requires inspection service on a holiday or a day designated in lieu of a holiday, such service is considered holiday work. The official plant must, in advance of such

holiday work, request that the inspector in charge furnish inspection services during such period and must pay the Agency for such holiday work at the hourly rate. For each calendar year, FSIS will calculate the holiday rate for inspection service, per hour per program employee, using the following formula: The quotient of dividing the Office of Field Operations plus Office of International Affairs inspection program personnel's previous fiscal year's regular direct pay by previous fiscal year's regular hours, plus the quotient multiplied by the calendar year's percentage of cost of living increase, multiplied by 2, plus the benefits rate, plus the travel and operating rate, plus the overhead rate, plus the allowance for bad debt rate. FSIS calculates the benefits rate, the travel and operating rate, the overhead rate, and the allowance for bad debt using the formulas set forth in § 592.510(b), and the cost of living increases and percentage of inflation factors set forth in § 592.510(c).

[71 FR 2143, Jan. 13, 2006, as amended at 76 FR 20229, Apr. 12, 2011]

SANITARY AND PROCESSING REQUIREMENTS

§ 592.600 General.

Except as otherwise approved by the Administrator, the sanitary, processing, and facility requirements, as applicable, shall be the same for the product processed under this part as for egg products processed under part 590 of this chapter.

§ 592.650 Inspection.

Examinations of the ingredients, processing, and the product shall be made to ensure the production of a wholesome, unadulterated, and properly labeled product. Such examinations include, but are not being limited to:

(a) Sanitation checks of plant premises, facilities, equipment, and processing operations.

(b) Checks on ingredients and additives used in products to ensure that they are not adulterated, are fit for use as human food, and are stored, handled, and used in a sanitary manner.

(c) Examination of the eggs or egg products used in the products to ensure they are wholesome, not adulterated, and comply with the temperature, pasteurization, or other applicable requirements.

(d) Inspection during the processing and production of the product to determine compliance with any applicable standard or specification for such product.

(e) Examination during processing of the product to ensure compliance with approved formulas and labeling.

(f) Test weighing and organoleptic examinations of finished product.

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381.36 (f) added 49633
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381.65 (e) and (f) redesignated as (f) and (e); new (f) revised; (g) and (h) added 49634
381.66 (b) and (e) revised; (c)(3) and (4) removed 49634
381.69 Added 49635
381.76 Heading, (a), (b)(1) introductory text, (iv) and (2) revised; (b)(1)(v) and (6) added 49635
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