SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

PART 412—LABEL APPROVAL

Sec.
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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 determined to be eligible to export such products to the United States under § 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 determined to be eligible to export such products to the United States under § 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; 84 FR 65268, Nov. 27, 2019]

§ 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.

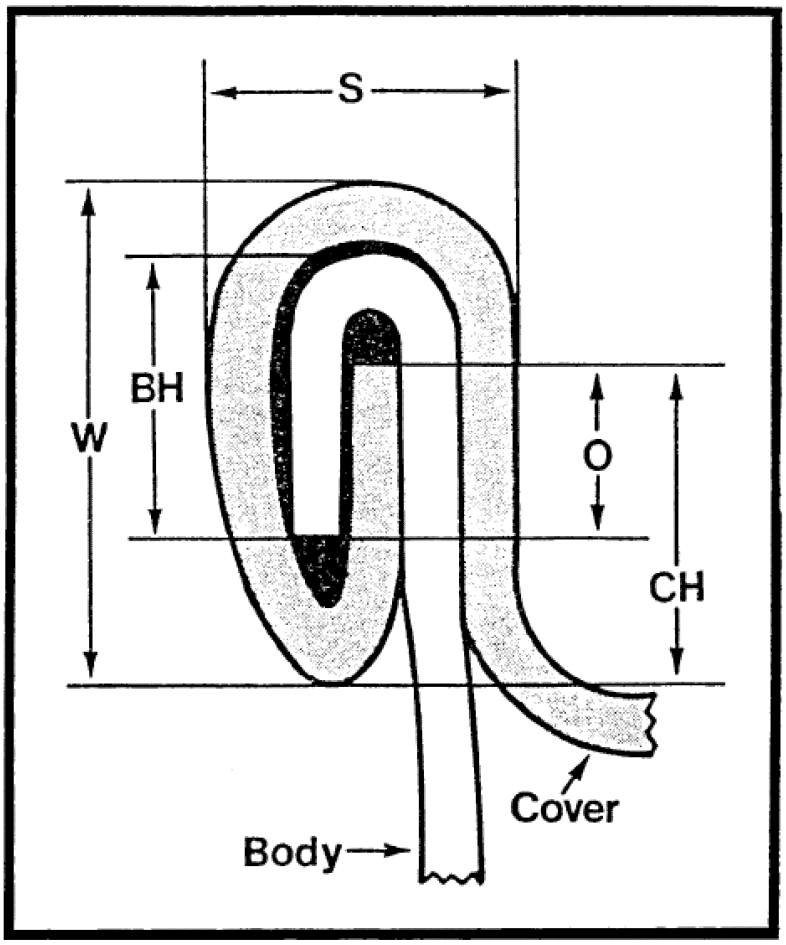

Figure 1 to § 431.2—Micrometer Measurement of Cylindrical Containers

(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

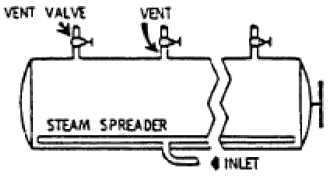

Figure 1.

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

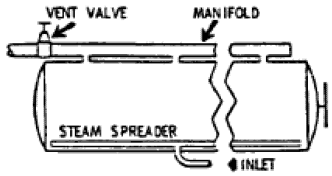

Figure 2.

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

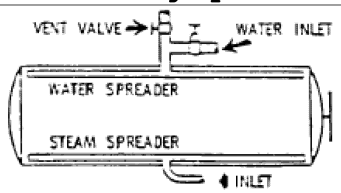

Figure 3.

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

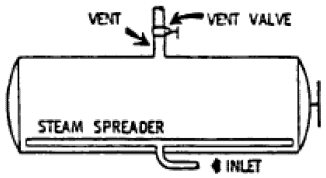

Figure 4.

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

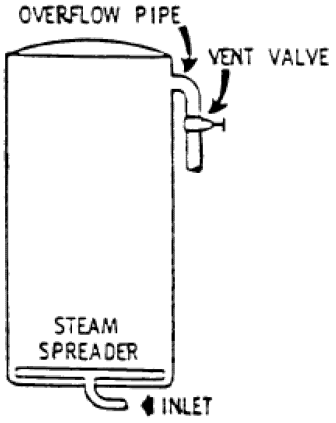

Figure 5.

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

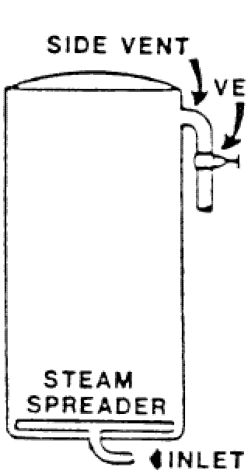

Figure 6

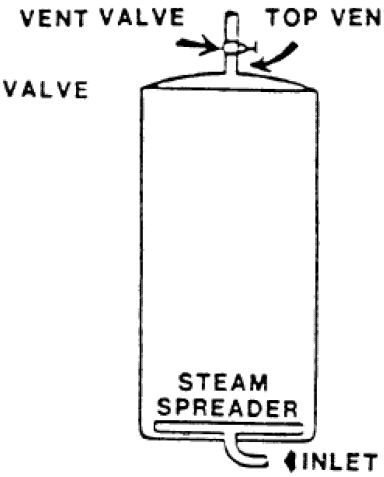

Figure 7

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.

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.