Subparts B—F [Reserved]

Subpart G—Canning and Canned Products

AUTHORITY: 7 U.S.C. 38f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

Subpart A—General

SOURCE: 35 FR 15586, Oct. 3, 1970, unless otherwise noted.

§ 318.1 Products and other articles entering official establishments.

(a) Except as otherwise provided in paragraphs (g) and (h) of this section or §318.12, no product shall be brought into an official establishment unless it has been prepared only in an official establishment and previously inspected and passed by a Program employee, and is identified by an official inspection legend as so inspected and passed. Notwithstanding the foregoing provisions of this subparagraph, product imported in accordance with part 327 of this subchapter and not prepared in the United States outside an official establishment, may enter any official establishment subject in other respects to the same restrictions as apply to domestic product. Products received in an official establishment during the Program employees absence shall be identified and maintained in a manner acceptable to such employee. Product entering any official establishment shall not be used or prepared thereat until it has been reinspected in accordance with §318.2. Any product originally prepared at any official establishment may not be returned into any part of such establishment, except the receiving area approved under §318.3, until it has been reinspected by the inspector.

(b) No slaughtered poultry or poultry product shall be brought into an official establishment unless it has been (1) previously inspected and passed and is identified as such in accordance with the requirements of the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) and the regulations thereunder, and has not been prepared other than in an establishment inspected under said Act, or (2) has been inspected and passed and is identified as such in accordance with the requirements of a State law.

(c) Every article for use as an ingredient in the preparation of meat food products, when entering any official establishment and at all times while it is in such establishment, shall bear a label showing the name of the article, the amount or percentage therein of any substances restricted by this part or part 317 of this subchapter, and a list of ingredients in the article if composed of two or more ingredients: *Provided,* That in the case of articles received in tank car lots, only one such label shall be used to identify each lot. In addition, the label must show the name and address of the shipper.

(d) Containers of preparations which enter any official establishment for use in hog scalding water or in denuding of tripe shall bear labels showing the chemical names of the preparations. In the case of any preparation containing any of the chemicals which are specifically limited by §318.7(c)(4) as to amount permitted to be used, the labels on the containers must also show

the percentage of each such chemical in the preparation and must provide dilution directions which prescribe the maximum allowable use concentration of the preparations.

(e) Dyes, chemicals, or other substances the use of which is restricted to certain products may be brought into or kept in an official establishment only if such products are prepared thereat. No prohibited dye, chemical, preservative, or other substance shall be brought into or kept in an official establishment.

(f) [Reserved]

(g) Glands and organs, such as cotyledons, ovaries, prostate glands, tonsils, spinal cords, and detached lymphatic, pineal, pituitary, parathyroid, suprarenal, pancreatic and thyroid glands, used in preparing pharmaceutical, organotherapeutic, or technical products and which are not used as human food (whether or not prepared at official establishments) may be brought into and stored in edible product departments of inspected establishments if packaged in suitable containers so that the presence of such glands and organ will in no way interfere with the maintenance of sanitary conditions or constitute an interference with inspection. Glands or organs which are regarded as human food products, such as livers, testicles, and thymus glands, may be brought into official establishments for pharmaceutical, organotherapeutic or technical purposes, only if U.S. inspected and passed and so identified. Lungs and lung lobes derived from livestock slaughtered in any establishment may not be brought into any official establishment except as provided in §318.12(a).

(h)(1) Carcasses of game animals, and carcasses derived from the slaughter by any person of livestock of his own raising in accordance with the exemption provisions of paragraph 23(a) of the Act, and parts of such carcasses, may be brought into an official establishment for preparation, packaging, and storing in accordance with the provisions of §303.1(a)(2) of this subchapter.

(2) Meat, meat byproducts, and meat food products bearing official marks showing that they were inspected and passed under State inspection in any State not designated in §331.2 of this subchapter may be received by official establishments for storage and distribution solely in intrastate commerce. The presence of such State inspected products must not create any unsanitary condition or otherwise result in adulteration of any products at the official establishment or interfere with the conduct of inspection under this subchapter. In addition, such State inspected products must be stored separately and apart from the federally inspected products in the official establishment.

(i) The operator of the official establishment shall furnish such information as is necessary to determine the origin of any product or other article entering the official establishment. Such information shall include, but is not limited to, the name and address of the seller or supplier, transportation company, agent, or broker involved in the sale or delivery of the product or article in question.

(j) Any product or any poultry or poultry product or other article that is brought into an official establishment contrary to any provision of this section may be required by the Administrator to be removed immediately from such establishment by the operator thereof, and failure to comply with such requirement shall be deemed a violation of this regulation. If any slaughtered poultry or poultry products or other articles are received at an official establishment and are suspected of being adulterated or misbranded under the Poultry Products Inspection Act or the Federal Food, Drug, and Cosmetic Act, or applicable State laws, the appropriate governmental authorities will be notified.

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 38 FR 5152, Feb. 26, 1973; 48 FR 6091, Feb. 10, 1983; 49 FR 32055, Aug. 10, 1984]

§318.2 Reinspection, retention, and disposal of meat and poultry products at official establishments.

(a) All products and all slaughtered poultry and poultry products brought into any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment and

shall be subject to reinspection by a Program employee at the official establishment in such manner and at such times as may be deemed necessary to assure compliance with the regulations in this subchapter.

(b) All products, whether fresh, cured, or otherwise prepared, even though previously inspected and passed, shall be reinspected by Program employees as often as they may deem necessary in order to ascertain that they are not adulterated or misbranded at the time they enter or leave official establishments and that the requirements of the regulations in this subchapter are complied with.

(c) Reinspection may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The circuit supervisor shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.[1]

(d) A U.S. retained tag shall be placed by a Program employee at the time of reinspection at any official establishment on all products which are suspected on such reinspection of being adulterated or misbranded, and such products shall be held for further inspection. Such tags shall be removed only by authorized Program employees. When further inspection is made, if the product is found to be adulterated, all official inspection legends or other official marks for which the product is found to be ineligible under the regulations in this subchapter, shall be removed or defaced and the product will be subject to condemnation and disposal in accordance with part 314 of this subchapter, except that a determination regarding adulteration may be deferred if a product has become soiled or unclean by falling on the floor or in any other accidental way or if the product is affected with any other condition which the inspector deems capable of correction, in which case the product shall be cleaned (including trimming if necessary) or otherwise handled in a manner approved by the inspector to assure that it will not be adulterated or misbranded and shall then be presented for reinspection and disposal in accordance with this section. If upon final inspection, the product is found to be neither adulterated nor misbranded, the inspector shall remove the U.S. retained tag. If a product is found upon reinspection to be misbranded, it shall be held under a U.S. retained tag, or a U.S. detention tag as provided in part 329 of this subchapter, pending correction of the misbranding or issuance of an order under section 7 of the Act to withhold from use the labeling or container of the product, or the institution of a judicial seizure action under section 403 of Act or other appropriate action. The inspector shall make a complete record of each transaction under this paragraph and shall report his action to the area supervisor.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 318.3 Designation of places of receipt of products and other articles for reinspection.

Every official establishment shall designate, with the approval of the circuit supervisor, a dock or place at which products and other articles subject to reinspection under § 318.2 shall be received, and such products and articles shall be received only at such dock or place.

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

(a) All processes used in curing, pickling, rendering, canning, or otherwise preparing any product in official establishments shall be supervised by Program employees unless such preparation is conducted as a custom operation exempted from inspection under

[1] Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisors of Program circuits. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved, such as liver, oxtails, etc.

§ 303.1(a)(2) of this subchapter in any official establishment or consists of operations that are exempted from inspection under § 303.1(d) of this subchapter and are conducted in a retail store in an establishment subject to inspection only because the State or Territory in which the establishment is located is designated under paragraph 301(c) of the Act. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. In order to carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to assure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter. The effectiveness of such measures will be subject to review by the Department.

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing meat food product who has a total plant quality control system or plan for controlling such product, after antemortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner of operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control system requires it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of an establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will be responsible for the quality control system.

(3) A list identifying those parts and sections of the Federal meat inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the quality control system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters or limits which will be used, and the points at which corrective action will occur and the nature of such corrective action—ranging from

least to most severe: *Provided,* That, subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) *Partial Quality Control Programs.* (1) Any owner or operator of an official establishment preparing meat food products who is required to have a quality control program for a product operation, or part of an operation shall make the written program and data and information generated by the program available to Program employees.

(2)(i) This quality control program shall include, as appropriate for the operation which the program concerns, detailed information on: raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits that will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action—ranging from the least to the most severe.

(ii) This quality control program shall ensure that the product, operation, or part of an operation which it concerns is in control and that applicable product or label limits are being met. Process control is to be determined by generally recognized statistical process control procedures.

(e) *Evaluation and Approval of Total Plant Quality Control.* (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section. If it is determined by the Administrator, on the basis of the evaluation, that the total quality control system will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with the notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities under the Act.

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by parts 316 and 317 of this subchapter.

(g) *Termination of Total Plant Quality Control.* (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(h)(1) *Operating Schedule Under Total Plant Quality Control.* An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permission will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in §318.4(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspection services at the discretion of the circuit supervisor and charged for such services.

(Reporting requirements were approved by the Office of Management and Budget under control number 0583–0015)

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 12003, June 24, 1971; 45 FR 54322, Aug. 15, 1980; 51 FR 32304, Sept. 11, 1986; 62 FR 45024, Aug. 25, 1997; 62 FR 54759, Oct. 22, 1997]

§ 318.5 Requirements concerning procedures.

(a)(1) Care shall be taken to assure that product is not adulterated when placed in freezers. If there is doubt as to the soundness of any frozen product, the inspector will require the defrosting and reinspection of a sufficient quantity thereof to determine its actual condition.

(2) Frozen product may be defrosted in water or pickle in a manner and with the use of facilities which are acceptable to the inspector. Before such product is defrosted, a careful examination shall be made to determine its condition. If necessary, this examination shall include defrosting of representative samples by means other than in water or pickle.

(b) Product, such as pork tenderloins, brains, sweetbreads, stew, or chop suey, shall not be packed in hermetically sealed metal or glass containers, unless subsequently heat processed or otherwise treated to preserve the product in a manner approved by the Administrator in specific cases.

(c) Care shall be taken to remove bones and parts of bones from product which is intended for chopping.

(d) Heads for use in the preparation of meat food products shall be split and the bodies of the teeth, the turbinated and ethmoid bones, ear tubes, and horn butts removed, and the heads then thoroughly cleaned.

(e) Kidneys for use in the preparation of meat food products shall first be freely sectioned and then thoroughly soaked and washed. All detached kidneys, including beef kidneys with detached kidney fat, shall be inspected before being used in or shipped from the official establishment.

(f) Cattle paunches and hog stomachs for use in the preparation of meat food products shall be thoroughly cleaned on all surfaces and parts immediately after being emptied of their contents, which shall follow promptly their removal from the carcasses.

(g) Clotted blood shall be removed from hog hearts before they are shipped from the official establishment or used in the preparation of meat food products.

(h) Beef rounds, beef bungs, beef middles, beef bladders, calf rounds, hog bungs, hog middles, and hog stomachs which are to be used as containers of any meat food product shall be presented for inspection, turned with the fat surface exposed.

(i) Portions of casings which show infection with Oesophagostomum or other nodule-producing parasite, and weasands infected with the larvae of Hypoderma lineatum, shall be rejected, except that when the infestation is slight and the nodules and larvae are removed, the casing or weasand may be passed.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 318.6 Requirements concerning ingredients and other articles used in preparation of products.

(a) All ingredients and other articles used in the preparation of any product shall be clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated. Official establishments shall furnish inspectors accurate information on all procedures involved in product preparation including product composition and any changes in such procedures essential for inspectional control of the product.

(b)(1) The only animal casings that may be used as containers of product are those from cattle, sheep, swine, or goats.

(2) Casings for products shall be carefully inspected by Program employees. Only those casings which have been carefully washed and thoroughly flushed with clean water immediately before stuffing and are suitable for containers, are clean, and are passed on such inspection shall be used, except that preflushed animal casings packed in salt or salt and glycerine solution or other approved medium may be used without additional flushing provided they are found to be clean and otherwise acceptable and are thoroughly rinsed before use.

(3) Hog and sheep casings intended for use as containers of product may be treated by soaking in or applying thereto sound, fresh pineapple juice or papain or bromelin or pancreatic extract to permit the enzymes contained in these substances to act on the casings to make them less resistant. The casings shall be handled in a clean and sanitary manner throughout and the treatment shall be followed by washing and flushing the casings with water sufficiently to effectively remove the substance used and terminate the enzymatic action.

(4) On account of the invariable presence of bone splinters, detached spinal cords shall not be used in the preparation of edible product other than for rendering where they constitute a suitable raw material.

(5) Testicles if handled as an edible product may be shipped from the official establishment as such, but they shall not be used as an ingredient of a meat food product.

(6) Tonsils shall be removed and shall not be used as ingredients of meat food products.

(7) Blood from livestock prepared in accordance with §310.20 of this subchapter may be used as an ingredient of a meat food product for which a standard is prescribed in part 319 of this subchapter, if permitted by such standard, and may be used in any meat food product for which no such standard is prescribed in part 319 of this subchapter if it is a common and usual ingredient of such product.

(8) Intestines shall not be used as ingredients in any meat food product for which a standard is prescribed in part 319 of this subchapter and shall not be used in other products unless the products are labeled in accordance with §317.8(b)(3) of this subchapter.

(9) Poultry products and egg products (other than shell eggs) which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when identified as having been inspected and passed for wholesomeness by the Department under the regulations in 7 CFR part 59 or 9 CFR part 362 or 381 and when found to be sound and otherwise acceptable when presented for use. Poultry products and egg products (other than shell eggs) which have not been so inspected and passed for wholesomeness shall not be used in the preparation of such meat food products.

(10) Dry milk products which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when produced in a plant approved by the Department under the regulations in 7 CFR part 58, and when found to be sound and otherwise acceptable when presented for use. Dry milk products prepared in a plant not so approved shall not be used in the preparation of such meat food products.

(11) [Reserved]

(12) Ingredients for use in any product may not bear or contain any pesticide chemical or other residues in excess of level permitted in §318.16.

(13) Use of ''Mechanically Separated (Kind of Poultry),'' as defined in §381.173 of this chapter, in the preparation of meat food products shall accord with §381.174 and all other applicable provisions of this subchapter.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 14368, June 1, 1973; 38 FR 29214, Oct. 23, 1973; 39 FR 1973, Jan. 16, 1974; 41 FR 23702, June 11, 1976; 49 FR 19623, May 9, 1984; 50 FR 6, Jan. 2, 1985; 60 FR 55982, Nov. 3, 1995]

§318.7 Approval of substances for use in the preparation of products.

(a)(1) No substance may be used in the preparation of any product unless it is approved in paragraph (c)(4) of this section or elsewhere in part 318 or in part 319 of this subchapter, or by the Administrator in specific cases.

(2) Approval of new substances or new uses or new levels of use of approved substances may be granted by the Administrator if:

(i) The substance has been previously approved by the Food and Drug Administration (FDA) for use in meat or meat food products as a food additive, color additive, or as a substance generally recognized as safe and is listed in title 21 of the Code of Federal Regulations, parts 73, 74, 81, 172, 173, 179, 182 or 184.

(ii) Its use is in compliance with applicable FDA requirements; and

(iii) The Administrator has determined that:

(A) The use of the substance will not render the product in which it is used adulterated or misbranded or otherwise not in compliance with the requirements of the Act; and

(B) Its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the stated technical effect as determined in specific cases.

(3) Whenever the Administrator determines that approval of a new substance or new use or new level of use of an approved substance should be granted in accordance with paragraph (a)(2) of this section, the Administrator shall issue a final rule amending the chart of substances in paragraph (c)(4) of this section to include the additional substance or new use of the substance, and any technical effect or change in level of use of the substance.

(4) No product shall bear or contain any substance which would render it adulterated or misbranded, or which is not approved in part 318 or part 319 of this subchapter, or by the Administrator in specific cases.

(b) Requirements for the use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon. Nitrates shall not be used in curing 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.

(2) 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 chromotography 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 nitorosamines 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 if 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 assure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat food product 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 makesadjustments 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: *Provided, however,* That 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 subparagraph shall be made on pumped bacon cooked 340 °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.

(3) Notwithstanding the provisions of paragraph (b)(1) of this section, sodium nitrite may be used at:

(i) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 500 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; provided that the establishment has a partial quality control program as provided in §318.4(d) that results in compliance with this provision, or

(ii) 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 growth of botulinum toxin at a level sufficient for the purpose of preventing the growth of botulinum toxin; provided that the establishment has a partial quality control program as provided in §318.4(d) that results in compliance with this provision.

(4) The Department shall collect samples of bacon from plants producing under paragraph (b)(3) 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)(2) 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 plant shall become subject to the provisions of paragraph (b)(2) of this section.

(5) *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.

(6) *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) Under appropriate declaration as required in parts 316 and 317 of this subchapter, the following substances may be added to products:

(1) 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 substances specified in the chart in paragraph (c)(4) of this section may be added to products under conditions, if any, specified in this part or in part 317 of this subchapter.

(2) Other harmless artificial flavorings may be added to products

with the approval of the Administrator in specific cases.

(3) Coloring matter and dyes other than those specified in the chart in paragraph (c)(4) of this section may be applied to products, 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.

(4) The substances specified in the following chart are acceptable for use in the preparation of products, provided they are used for the purposes indicated, within the limits of the amounts stated and under other conditions specified in this part and part 317 of this subchapter. In addition to the substances listed in the following chart, part 319 of this subchapter specifies other substances that are acceptable in preparing specified products.

Class of substance	Substance	Purpose	Products	Amount	
Acidifiers	Acetic acid	To adjust acidity	Various[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 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 blood of livestock, not more than 2 parts of water to 1 part of sodium citrate shall be used.	
Antifoaming agent	Methyl polysilicone	To retard foaming	Soups	10 parts per million.	
			Rendered fats	Do.	
			Curing pickle	50 parts per million.	
Antioxidants and oxygen interceptors.	BHA (butylated hydroxyanisole).	To retard rancidity	Dry sausage	0.003 percent based on total weight.	.006 percent in combination.
	BHT (butylated hydroxytoluene).	...do	...do	...do	
	Propyl gallate	...do	...do	...do	
	TBHQ (tertiary butylhydroquinone).	...do	...do	...do	0.006 percent in combination only with BHA and/or BHT.
	BHA (butylated hydroxyanisole).	...do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination.
	BHT (butylated hydroxytoluene).	...do	...do	...do	
	Glycine	...do	...do	...do	
	Propyl gallate	...do	...do	...do	
	Resin guaiac	...do	...do	...do	
	TBHQ (tertiary butylhydroquinone).	...do	...do	...do	0.02 percent in combination only with BHA and/or BHT.

	Tocopherols	.....do	.....do	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 sausage, pregrilled beef patties, and restructured meats.	Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants.	
	BHA (butylated hydroxyanisole).	.....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 based on fat content.
	BHT (butylated hydroxytoluene).	.....do	.....do	.....do	
	Propyl gallate	.....do	.....do	.....do	
	TBHQ (tertiary butylhydroquinone).	.....do	.....do	.....do	0.02 percent in combination only with BHA and/or BHT based on fat content.
	BHA (butylated hydroxyanisole).	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination.
	BHT (butylated hydroxytoluene).	.....do	.....do	.....do	
	Propyl gallate	.....do	.....do	.....do	
	TBHQ (tertiary butylhydroquinone).	.....do	.....do	.....do	0.01 percent in combination only with BHA and/or BHT.
	BHA (butylated hydroxyanisole).	.....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.	
	BHT (butylated hydroxytol-) uene).	.....do	.....do	Do.	
	Octyl gallate	.....do	.....do	Do.	
	Propyl gallate	.....do	.....do	Do.	
	Dodecyl gallate	.....do	.....do	Do.	
	Ascorbyl palmitate	.....do	.....do	Do.	

	Ascorbyl stearate	....do	....do	Do.
	TBHQ (tertiary butylhydroquinone).	....do	....do	0.02 percent alone or in combination only with BHA and/or BHT based on fat or oil content.

Class of substance	Substance	Purpose	Products	Amount
Binders and extenders.	Agar-agar	To stabilize and thicken.	Thermally processed canned jellied meat food products	0.25 percent of finished product.
	Algin	To extend and stabilize product	Breading mix; sauces	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. Ingredients of mixture must be added dry.
	Bread	To bind and extend product.	Bockwurst	3.5 percent individually or collectively with other binders.
	Calcium reduced dried skim milk.	....do	Sausages as provided in part 319.	Do.
	....do	....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders.
	....do	....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders.
	Carrageenan	To extend and stabilize product	Breading mix; sauces	Sufficient for purpose in accordance with 21 CFR 172.5.
	Carboxymethyl cellulose (cellulose gum)	....do	Baked pies	Do.
	Cereal	To bind and extend product.	Sausages as provided in part 319, bockwurst	3.5 percent individually or collectively with other binders.
	....do	....do	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
	Dried milk	....do	Sausage as provided in part 319.	3.5 percent individually or collectively with other binders.
	....do	....do	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
	Enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate	To bind and extend product.	Sausages as provided in part 319.	3.5 percent total finished product. (Calcium lactate required at rate of 10 percent of binder).
	....do	....do	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5 (Calcium lactate required at rate of 10 percent of binder).
	Enzyme (rennet) treated sodium caseinate and calcium lactate	....do	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5. (Calcium lactate required at rate of 25 percent of binder).
	Gums, vegetable	....do	Egg roll	Sufficient for purpose in accordance with 21 CFR 172.5.

Class of substance	Substance	Purpose	Products	Amount
	Methyl cellulose	To extend and to stabilize product (also carrier)	Meat and vegetable patties.	0.15 percent.
	Isolated soy protein	To bind and extend product.	Sausage as provided in Part 319, bockwurst	2 percent.
	.....do	.....do	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5.
	.....do	.....do	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
	.....do	.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders and extenders.
	Sodium caseinate	.....do	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5.
	.....do	.....do	Sausage as provided in Part 319..	2 percent in accordance with 21 CFR 182.1748.
	.....do	.....do	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders and extenders in accordance with 21 CFR 182.1748.
	.....do	.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders and extenders in accordance with 21 CFR 182.1748.
	Dry or dried whey	To bind or thicken	Sausage as provided in Part 319, bockwurst	3.5 percent individually or collectively with other binders and extenders.
	Reduced lactose whey	.....do	.....do	Do.
	Reduced minerals whey	.....do	.....do	Do.
	Whey protein concentrate.	.....do	.....do	Do. In accordance with 21 CFR 184.1979c.
	Dry or dried whey	.....do	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5.
	Reduced lactose whey	.....do	.....do	Do.
	Reduced minerals whey	.....do	.....do	Do.
	Whey protein concentrate.	.....do	.....do	Do. In accordance with 21 CFR 184.1979c.
	Dry or dried whey	.....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.
	Reduced lactose whey	.....do	.....do	Do.
	Reduced minerals whey	.....do	.....do	Do.
	Whey protein concentrate.	.....do	.....do	Do. In accordance with 21 CFR 184.1979c.
	.....do	To bind meat pieces	Restructured meat food products, whole muscle meat cuts	3.5 percent individually or collectively with other binders and extenders. In accordance with 21 CFR 184.1979c.
	Soy flour	To bind and extend product.	Sausage as provided in Part 319, bockwurst	3.5 percent individually or collectively with other binders and extenders.
	Soy protein concentrate	.....do	.....do	Do.
	Starchy vegetable flour	.....do	.....do	Do.
	Vegetable starch	.....do	.....do	Do.
	Wheat gluten	.....do	.....do	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrin	.....do	.....do	Do. In accordance with 21 CFR 184.1277.
	Soy flour	.....do	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders and extenders.

Class of substance	Substance	Purpose	Products	Amount
	Soy protein concentrate	.....do	.....do	Do.
	Starchy vegetable flour	.....do	.....do	Do.
	Vegetable starch	.....do	.....do	Do.
	Wheat gluten	.....do	.....do	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrin	.....do	.....do	Do. In accordance with 21 CFR 184.1277.
	Soy flour	.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders and extenders.
	Soy protein concentrate	.....do	.....do	Do.
	Wheat gluten	.....do	.....do	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrin	.....do	.....do	Do. In accordance with 21 CFR 184.1277.
	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.
	Carrageenan	To prevent purging of brine solution.	Cured pork products as provided in 9 CFR 319.104.	Not to exceed 1.5 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, and 172.626.
	Food starch modified	.....do	.....do	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 172.892.
	Sodium caseinate	.....do	.....do	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.
	Isolated soy protein	.....do	.....do	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products.
	Carrageenan, Locust bean gum, and Xanthan gum blend..	To prevent purging of solution..	Cured pork products as provided in 9 CFR 319.104(d)..	In combination, not to exceed 0.5 percent of product 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.
Bleaching agent	Hydrogen peroxide	To remove color	Tripe (substance must be removed from product by rinsing with clear water).	

Class of substance	Substance	Purpose	Products	Amount
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	Do.
Coloring agents (natural).	Alkanet, annatto, carotene cochineal, green chlorophyl, saffron and tumeric.	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product.	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar).
Coloring agents (artificial).	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).	...do	...do	Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt or sugar).
	Titanium dioxide	...do	Canned ham salad spread and creamed type canned products.	0.5 percent.
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 comminuted meat food product.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Erythorbic acid	...do	...do	Do.
	Fumaric acid	To accelerate color fixing.	Cured, comminuted meat or meat food products.	0.065 percent (or 1 oz to 100 lb) of the weight of the meat or meat byproducts, before processing.
	Glucone delta lactone	To accelerate color fixing.	Cured, comminuted meat or meat food product.	8 oz to each 100 lb of meat or meat byproduct.
			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, the following: 8 oz in 100 lb of the 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.	87.5 oz to 100 gal pickle at 10 percent pump level; ⅞ oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts 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	...do	...do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Citric acid or sodium citrate.	.....do	.....do	May be used in cured products or in 10 percent solution used to spray surfaces of cured cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used.
Curing agents	Sodium or potassium nitrate.	Source of nitrite	Cured products other than bacon. Nitrates may not be used in baby, junior, and toddler foods.	7 lb to 100 gal pickle; 3½ oz to 100 lb meat (dry cure); 2¾ oz to 100 lb chopped meat.
	Sodium or potassium nitrite. (Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely 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 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 (dry cure); ¼ oz to 100 lb chopped meat and/or meat byproduct. The use of nitrites, nitrates, or combination shall not result in more than 200 parts per million 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	Acetylated monoglycerides.	To emulsify product ...	Shortening	Do.
	Diacetyl tartaric acid esters of mono- and diglycerides.	.....do	Rendered animal fat or a combination of such fat with vegetable fat.	Do.
	Glycerol-lacto stearate, oleate, or palmitate.	.....do	.....do	Do.
	Lecithin	To emulsify product (also as an Antioxidant).	Oleomargarine, shortening, various meat food 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.
	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
	Polygylcerol esters of fatty acids (polygylcerol 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 or composition; oleomargaine.	Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5 percent for oleomargarine.
	1,2-propylene glycol esters of fatty acids.	.....do	Margarine or oleomargarine.	2.0 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.	1 percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 percent.
	Propylene glycol mono and diesters of fats and fatty acids.	.....do	Rendered animal fat or a combination of such fat with vegetable fat.	Sufficient for purpose.
	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.	1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 percent.
	Stearyl-2-lactylic acid	.....do	Shortening to be used for cake icings and fillings.	3.0 percent.
	Stearyl monoglyceridyl citrate.	.....do	Shortening	Sufficient for purpose.
Film forming agents	A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethyl-cellulose, 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% 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 [2]	Do.
	Smoke flavoring	.....do	.....do	Do.
	Autolyzed yeast extract	.....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 growth of *Clostridium botulinum*.	Bacon	Sufficient for purpose.
	Benzoic acid (sodium, potassium and calcium salts).	To retard flavor reversion.	Margarine or oleomargarine.	0.1 percent individually, or if used in combination or with sorbic acid and its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).

Class of substance	Substance	Purpose	Products	Amount
	Calcium lactate	To protect flavor	Cooked semi-dry and dry products including sausage, imitation sausage, and non-specific meat food sticks.	0.6 percent in product formulation.
	Citric acid	Flavoring	Chili con carne	Sufficient for purpose.
	Corn syrup solids, corn syrup, glucose syrup.	To flavor	Sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham.	Sufficient for purpose.
	Dextrose	To flavor product	Sausage, ham and cured products.	Sufficient for purpose.
	Diacetyl	...do	Oleomargarine	Do.
	Disodium guanylate	...do	Various[2]	Do.
	Disodium inosinate	...do	...do	Do.
	Hydrolyzed plant protein	...do	...do	Do.
	Isopropyl citrate	To protect flavor	Oleomargarine	0.02 percent.
	Malt syrup	To flavor product	Cured products	2.5 percent.
	Milk protein hydrolysate	...do	Various[2]	Sufficient for purpose.
	Monosodium glutamate	...do	...do	Do.
	Monoammonium glutamate.	...do	...do	Do.
	Sodium sulfoacetate derivative of mono and diglycerides.	...do	...do	0.5 percent.
	Sodium tripoly-phosphate.	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.
	Mixtures of sodium tripolyphosphate and sodium metaphosphate, insoluble; and sodium polyphosphates, glassy.	...do	...do	Do.
	Sorbitol	To flavor, to facilitate the removal of casings from product, and to reduce carmelization and charring.	Cooked sausage labeled frankfurter, frank, furter, wiener, and knockwurst; cured pork and pork products, as provided in part 319 of this subchapter.	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	To protect flavor	...do	0.15 percent.
	Sugars (sucrose and dextrose).	To flavor product	Various[2]	Sufficient for purpose.
	Potassium lactate	To flavor product	Various meat and meat food products, except infant formula and infant food.[2]	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Sodium lactate	...do	...do	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1768.
	Sodium acetate	To flavor products	Various	Not to exceed 0.12 percent of formulate in accordance
	Sodium diacetate	...do	...do	Not to exceed 0.1 percent of formulate in accordance with 21 CFR 184.1754
Gases	Carbon dioxide solid (dry ice).	To cool product	Chopping of meat, packaging of product.	Do.

Class of substance	Substance	Purpose	Products	Amount
	Liquid nitrogen	Contact freeze	Various	Sufficient for purpose
	Nitrogen	To exclude oxygen	Sealed container	Do.
Hog scald agents; must be removed by subsequent cleaning operations.	Caustic soda	To remove hair	Hog carcasses	Do.
	Dimethylpolysiloxane	...do	...do	Do.
	Dioctyl sodium sulfosuccinate.	...do	...do	Do.
	Disodium-calcium ethylenediamine-tetraacetate.	...do.	...do.	Do.
	Disodium phosphate	...do	...do	Do.
	Ethylenediamine-tetraacetic acid (sodium salts).	...do	...do	Do.
	Lime (calcium oxide, calcium hydroxide).	...do	...do	Do.
	Potassium hydroxide	...do	...do	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.
	Sodium n-alkylbenzene sulfonate (alkyl group predominantly C_{12} and C_{13} and not less than 95 percent C_{10} and C_{16}.	...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	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination under quality control.	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).
	d- and dl-alphatocopherol.	To inhibit nitrosamine formation.	Pump-cured bacon	500 ppm; by injection or surface application.

Class of substance	Substance	Purpose	Products	Amount
	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 a 10 percent water solution prior to stuffing.
	Silicon dioxide	Processing aid/dispersant.	Tocopherol-containing bacon curing premixes.	At level not to exceed 4.0 percent in the dry mix.
	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).
	Calcium disodium, EDTA (calcium disodium ethylenediaminetetraacetate).	To preserve product and to protect flavor.	...do	75 parts per million by weight of the finished oleomargarine or margarine.
	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.
	Sodium bicarbonate	To neutralize excess acidity, cleaning vegetables.	Rendered fats, soups, curing pickle.	Sufficient for purpose.
	Calcium propionate	To retard mold growth	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
	Sodium propionate	...do	...do	Do.
	Sodium hydroxide	To decrease the amount of cooked out juices.	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.
	Disodium phosphate	...do	Meat food products except where otherwise prohibited by the Federal meat inspection regulations.	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in product (only clear solution may be injected into product).
	Monosodium phosphate	...do	...do	Do.
	Sodium metaphosphate, insoluble.	...do	...do	Do.
	Sodium polyphosphate, glassy.	...do	...do	Do.
	Sodium tripolyphosphate.	...do	...do	Do.
	Sodium pyrophosphate	...do	...do	Do.
	Sodium acid pyrophosphate.	...do	...do	Do.
	Dipotassium phosphate	...do	...do	Do.
	Monopotassium phosphate.	...do	...do	Do.
	Potassium tripolyphosphate.	...do	...do	Do.
	Potassium pyrophosphate.	...do	...do	Do.
	Citric acid (sodium and potassium salts).	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.
	Adipic acid	...do	...do	Do.
	Phosphoric acid	...do	...do	Do.
	Hydrochloric acid	...do	...do	Do.
	Sodium bicarbonate	To alkalize	...do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sodium carbonate	.....do	.....do	Do.
	Sodium hydroxide	.....do	.....do	Do.
	Potassium carbonate	.....do	.....do	Do.
	Potassium bicarbonate	.....do	.....do	Do.
	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 182.1033. (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 the product.)
	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 food products, e.g., ham.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
	Glycerine	Humecant	Shelf stable (Can Be stored at room temperature) meat snacks..	Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320
Proteolytic enzymes	Aspergillus oryzae	To soften tissues	Raw meat cuts	Solutions consisting of water and approved proteolytic enzymes applied or injected into raw meat cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavusoryzae group.	.....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	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.
Sources of radiation	Ionizing radiation limited to gamma rays from cobalt-60 or cesium-137.	To control *Trichinella spiralis*.	Pork carcasses, or fresh or previously frozen cuts of pork carcasses that have not been cured or heat-processed.	Minimum absorbed dose of 0.3 kiloGray (30 kilorads) to a maximum absorbed dose of 1 kiloGray (100 kilorads).
Artificial sweetners	Saccharin	To sweeten product	Bacon	0.01 percent.
Synergists (used in combination with antioxidants).	Citric acid	To increase effectiveness of antioxidants.	Any product permitted to contain antioxidants as provided in this part.	Not to exceed 0.01 percent based on fat content.
	Malic acid	.....do	Lard and shortening	0.01 percent based on total weight in combination with antioxidants.
	Monoisopropyl citrate	.....do	Lard, shortening, oleomargarine, fresh pork sausage, dried meats.	0.02 percent.
	Phosphoric acid	.....do	Lard and shortening	0.01 percent.

Class of substance	Substance	Purpose	Products	Amount
	Monoglyceride citrate	.....do	Lard, shortening, fresh pork sausage, dried meats.	0.02 percent.
Tenderizing agents	Aspergillus oryzae	To soften tissue	Raw meat cuts	Solutions consisting of water and approved proteolytic enzymes applied or injected into raw meat cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavus oryzae group.	.....do	.....do	Do.
	Bromelin	.....do	.....do	Do.
	Ficin	.....do	.....do	Do.
	Papain	.....do	.....do	Do.
	Potassium chloride	.....do	.....do	Not more than 3 percent of a 2.0 molar solution.
	Magnesium chloride	.....do	.....do	Not more than 3 percent of a 0.8 molar solution.
	Calcium chloride	.....do	.....do	Not more than 3 percent of a 0.8 molar solution.
	Potassium, magnesium or calcium chloride.	.....do	.....do	A solution of approved inorganic chlorides injected into or applied to raw meat 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 substance is approved may be obtained upon inquiry addressed to the Standards and Labeling Division, Meat and Poultry Inspection Technical Services, 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 § 317.4.

(d) No substance may be used in or on any product 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 food products, such as chopped and formed steaks or patties; or in any other meat food products consisting of fresh meat (with or without seasoning), except chorizo sausage, and except other meat food products in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.

(2) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid may not be used in cooked sausage or any other product; sulfurous acid and salts of sulfurous acid may not be used in or on any product and niacin or nicotinamide may not be used in or on fresh product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate may be used in or on any product only as provided in the chart in § 318.7(c)(4) or as approved by the Administrator in specific cases.

(Approved by the Office of Management and Budget under control number 0583–008)

[35 FR 15586, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 318.7, see the List of CFR Sections Affected in the Finding Aids section of this volume.

EFFECTIVE DATE NOTE: At 62 FR 61620, Nov. 19, 1997, § 318.7(c)(4) was amended by adding the entry for ''Carrageenan, Locust bean gum, and Xanthan gum blend'' under the class ''Binders and extenders'', effective January 20, 1998.

§ 318.8 Preservatives and other substances permitted in product for export only; handling; such product not to be used for domestic food purposes.

(a) Preservatives and other substances not permitted in domestic product under the regulations in this subchapter may be used in the preparation and packing of product intended

for export provided the product (1) accords to the specifications or directions of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; and (3) is labeled on the outside container to show that it is intended for export, and is otherwise labeled as required by this subchapter for such export product.

(b) The preparation and packing of export product as provided for in paragraph (a) of this section shall be done in a manner acceptable to the inspector in charge so that the identity of the export product is maintained conclusively and the preparation of domestic product is adequately protected. The preservatives and other substances not permitted in domestic product shall be stored in a room or compartment separate from areas used to store other supplies and shall be held under Program lock. Use of the preservatives or other substances shall be under the direct supervision of a Program employee.

(c) The packing of all articles under paragraph (a) of this section shall be conducted under the direct supervision of a Program employee.

(d) No article prepared or packed for export under paragraph (a) of this section shall be sold or offered for sale for domestic use or consumption, but unless exported shall be destroyed for food purposes under the direct supervision of a Program employee.

(e) The contents of the container of any article prepared or packed for export under paragraph (a) of this section shall not be removed, in whole or in part, from such container prior to exportation, except under the supervision of a Program employee. If such contents are removed prior to exportation, then the article shall be either repacked, in accordance with the provisions of paragraphs (b) and (c) of this section, or destroyed for food purposes under the direct supervision of a Program employee.

(f) Permission must be obtained from the Administrator before meats packed in borax are shipped from one official establishment to another or to an unofficial establishment for storage, except such meat prepared for the account of Federal agencies.

(g) At all times, the identity of meat to which borax has been added shall be effectively maintained. In no case shall such meat, nor any trimmings or fat derived from such meat, whether unwashed or washed, or otherwise treated, be diverted to domestic use.

(h) Salt used for bulking meat previously packed in borax may not again be used in an edible products department other than in connection with the packing of meat in borax. Only metal equipment should be used for handling such meat. Particularly effective cleansing will be required if wooden equipment such as trucks, washing vats, etc., is used. Boxes from which boraxed meat has been removed may be used for repacking meat in borax, but their use as containers for other meat will be dependent upon the effective removal of all traces of borax.

(i) The following instructions pertain to export cured pork packed in borax for the account of Federal agencies. The meat may be packed in borax in a room in which there is borax-free meat, provided proper care is taken to see that the borax-free meat is not affected by the borax. Under the same condition, meat packed in borax may be received, unpacked, defrosted, soaked, washed, smoked, and repacked in a room where there is other meat. However, meat originally packed in borax shall at all times be subject to the restrictions of meat so packed, even though repacked without borax. After packing or repacking, borax packed meat may be stored in a room with meat not packed in borax, provided a reasonable degree of separation is maintained between the two classes of product.

[35 FR 15586, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 38 FR 29214, Oct. 23, 1973]

§ 318.9 Samples of products, water, dyes, chemicals, etc., to be taken for examination.

Samples of products, water, dyes, chemicals, preservatives, spices, or other articles in any official establishment shall be taken, without cost to the Program, for examination, as often as may be deemed necessary for the efficient conduct of the inspection.

§ 318.10 Prescribed treatment of pork and products containing pork to destroy trichinae.

(a)(1) All forms of fresh pork, including fresh unsmoked sausage containing pork muscle tissue, and pork such as bacon and jowls, other than those covered by paragraph (b) of this section, are classed as products that are customarily well cooked in the home or elsewhere before being served to the consumer. Therefore, the treatment of such products for the destruction of trichinae is not required.

(2) Pork from carcasses or carcass parts that have been found free of trichinae as described under paragraph (e) or (f) of this section is not required to be treated for the destruction of trichinae.

(b) Products named in this paragraph, and products of the character hereof, containing pork muscle tissue (not including pork hearts, pork stomachs, and pork livers), or the pork muscle tissue which forms an ingredient of such products, shall be effectively heated, refrigerated, or cured to destroy any possible live trichinae, as prescribed in this section at the official establishment where such products are prepared: Bologna, frankfurter, vienna, and other cooked sausage; smoked sausage; knoblauch sausage; mortadella; all forms of summer or dried sausage, including mettwurst; flavored pork sausages such as those containing wine or similar flavoring materials; cured pork sausage; sausage containing cured and/or smoked pork; cooked loaves; roasted, baked, boiled, or cooked hams, pork shoulders, or pork shoulder picnics; Italian-style hams; Westphalia-style hams; smoked boneless pork shoulder butts; cured meat rolls; capocollo (capicola, capacola); coppa; fresh or cured boneless pork shoulder butts, hams, loins, shoulders, shoulder picnics, and similar pork cuts, in casings or other containers in which ready-to-eat delicatessen articles are customarily enclosed (excepting Scotch-style hams); breaded pork products; cured boneless pork loins; boneless back bacon; bacon used for wrapping around patties, steaks and similar products; and smoked pork cuts such as hams, shoulders, loins, and pork shoulder picnics (excepting smoked hams, and smoked pork shoulder picnics which are specially prepared for distribution in tropical climates or smoked hams delivered to the Armed Services); ground meat mixtures containing pork and beef, veal, lamb, mutton, or goat meat and other product consisting of mixtures of pork and other ingredients, which the Administrator determines at the time the labeling for the product is submitted for approval in accordance with part 317 of the regulations in this subchapter or upon subsequent reevaluation of the product, would be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product or otherwise. Cured boneless pork loins shall be subjected to prescribed treatment for destruction of trichinae prior to being shipped from the establishment where cured.

(c) The treatment shall consist of heating, refrigerating, or curing, as follows:

(1) *Heating.* (i) All parts of the pork muscle tissue shall be heated according to one of the time and temperature combinations in the following table:

Minimum internal temperature		Minimum time
Degrees fahrenheit	Degrees centigrade	
120	49.0	21 hours.
122	50.0	9.5 hours.
124	51.1	4.5 hours.
126	52.2	2 hours.
128	53.4	1 hour.
130	54.5	30 minutes.
132	55.6	15 minutes.
134	56.7	6 minutes.
136	57.8	3 minutes.
138	58.9	2 minutes.
140	60.0	1 minute.
142	61.1	1 minute.
144	62.2	Instant.

(ii) Time and temperature shall be monitored by a calibrated recording instrument that meets the requirements of paragraph (d) of this section, except for paragraph (c)(1)(iv).

(iii) The time to raise product temperature from 60 ° F. to 120 ° F shall not exceed 2 hours unless the product is cured or fermented.

(iv) Time, in combination with temperatures of 138 ° F to 143 ° F, need not be monitored if the product's minimum

thickness exceeds 2 inches (5.1 cm) and refrigeration of the product does not begin within 5 minutes of attaining 138 ° F (58.9 ° C).

(v) The establishment shall use procedures which insure the proper heating of all parts of the product. It is important that each piece of sausage, each ham, and other product treated by heating in water be kept entirely submerged throughout the heating period; and that the largest pieces in a lot, the innermost links of bunched sausage or other massed articles, and pieces placed in the coolest part of a heating cabinet or compartment or vat be included in the temperature tests.

(2) *Refrigerating.* At any stage of preparation and after preparatory chilling to a temperature of not above 40 °F. or preparatory freezing, all parts of the muscle tissue of pork or product containing such tissue shall be subjected continuously to a temperature not higher than one of those specified in table 1, the duration of such refrigeration at the specified temperature being dependent on the thickness of the meat or inside dimensions of the container.

TABLE 1—REQUIRED PERIOD OF FREEZING AT TEMPERATURE INDICATED

Temperature °F.	Group 1 (Days)	Group 2 (Days)
5	20	30
−10	10	20
−20	6	12

(i) Group 1 comprises product in separate pieces not exceeding 6 inches in thickness, or arranged on separate racks with the layers not exceeding 6 inches in depth, or stored in crates or boxes not exceeding 6 inches in depth, or stored as solidly frozen blocks not exceeding 6 inches in thickness.

(ii) Group 2 comprises product in pieces, layers, or within containers, the thickness of which exceeds 6 inches but not 27 inches, and product in containers including tierces, barrels, kegs, and cartons having a thickness not exceeding 27 inches.

(iii) The product undergoing such refrigeration or the containers thereof shall be so spaced while in the freezer as will insure a free circulation of air between the pieces of meat, layers, blocks, boxes, barrels, and tierces in order that the temperature of the meat throughout will be promptly reduced to not higher than 5 °F., −10 °F., or −20 °F., as the case may be.

(iv) In lieu of the methods prescribed in Table 1, the treatment may consist of commercial freeze drying or controlled freezing, at the center of the meat pieces, in accordance with the times and temperatures specified in Table 2.

TABLE 2—ALTERNATE PERIODS OF FREEZING AT TEMPERATURES INDICATED

Maximum internal temperature		Minimum Time
Degrees Fahrenheit	Degrees centi-grade	
0	−17.8	106 hours.
−5	−20.6	82 hours.
−10	−23.3	63 hours.
−15	−26.1	48 hours.
−20	−28.9	35 hours.
−25	−31.7	22 hours.
−30	−34.5	8 hours.
−35	−37.2	½ hour.

(v) During the period of refrigeration the product shall be kept separate from other products and in the custody of the Program in rooms or compartments equipped and made secure with an official Program lock or seal. The rooms or compartments containing product undergoing freezing shall be equipped with accurate thermometers placed at or above the highest level at which the product undergoing treatment is stored and away from refrigerating coils. After completion of the prescribed freezing of pork to be used in the preparation of product covered by paragraph (b) of this section the pork shall be kept under close supervision of an inspector until it is prepared in finished form as one of the products enumerated in paragraph (b) of this section or until it is transferred under Program control to another official establishment for preparation in such finished form.

(vi) Pork which has been refrigerated as specified in this subparagraph may be transferred in sealed railroad cars, sealed motortrucks, sealed trailers, or sealed closed containers to another official establishment at the same or another location, for use in the preparation of product covered by paragraph (b) of this section. Such vehicles and

containers shall be sealed and transported between official establishments in accordance with § 325.7 of this subchapter.

(3) *Curing*—(i) *Sausage.* The sausage may be stuffed in animal casings, hydrocellulose casings, or cloth bags. During any stage of treating the sausage for the destruction of live trichinae, except as provided in Method 5, these coverings shall not be coated with paraffin or like substance, nor shall any sausage be washed during any prescribed period of drying. In the preparation of sausage, one of the following methods may be used:

Method No. 1. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3⅓ pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3½ inches, measured at the time of stuffing, shall be held in a drying room not less than 20 days at a temperature not lower than 45 °F., except that in sausage of the variety known as pepperoni, if in casings not exceeding 1⅜ inches in diameter measured at the time of stuffing, the period of drying may be reduced to 15 days. In no case, however, shall the sausage be released from the drying room in less than 25 days from the time the curing materials are added, except that sausage of the variety known as pepperoni, if in casings not exceeding the size specified, may be released at the expiration of 20 days from the time the curing materials are added. Sausage in casings exceeding 3½ inches, but not exceeding 4 inches, in diameter at the time of stuffing, shall be held in a drying room not less than 35 days at a temperature not lower than 45 °F., and in no case shall the sausage be released from the drying room in less than 40 days from the time the curing materials are added to the meat.

Method No. 2. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3⅓ pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3½ inches, measured at the time of stuffing, shall be smoked not less than 40 hours at a temperature not lower than 80 °F., and finally held in a drying room not less than 10 days at a temperature not lower than 45 °F. In no case, however, shall the sausage be released from the drying room in less than 18 days from the time the curing materials are added to the meat. Sausage exceeding 3½ inches, but not exceeding 4 inches, in diameter at the time of stuffing, shall be held in a drying room, following smoking as above indicated, not less than 25 days at a temperature not lower than 45 °F., but in no case shall the sausage be released from the drying room in less than 33 days from the time the curing materials are added to the meat.

Method No. 3. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3⅓ pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After admixture with the salt and other curing materials and before stuffing, the ground or chopped meat shall be held at a temperature not lower than 34 °F. for not less than 36 hours. After being stuffed, the sausage shall be held at a temperature not lower than 34 °F. for an additional period of time sufficient to make a total of not less than 144 hours from the time the curing materials are added to the meat, or the sausage shall be held for the time specified in a pickle-curing medium of not less than 50° strength (salometer reading) at a temperature not lower than 44 °F. Finally, sausage having a diameter not exceeding 3½ inches, measured at the time of stuffing, shall be smoked for not less than 12 hours. The temperature of the smokehouse during this period at no time shall be lower than 90 °F.; and for 4 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 128 °F. Sausage exceeding 3½ inches, but not exceeding 4 inches, in diameter at the time of stuffing shall be smoked, following the prescribed curing, for not less than 15 hours. The temperature of the smokehouse during the 15-hour period shall at no time be lower than 90 °F., and for 7 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 128 °F. In regulating the temperature of the smokehouse for the treatment of sausage under this method, the temperature of 128 °F. shall be attained gradually during a period of not less than 4 hours.

Method No. 4. The meat shall be ground or chopped into pieces not exceeding one-fourth of an inch in diameter. A dry-curing mixture containing not less than 2½ pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After admixture with the salt and other curing materials and before stuffing, the ground or chopped sausage shall be held as a compact mass, not more than 6 inches in depth, at a temperature not lower than 36 °F. for not less than 10 days. At the termination of the holding period, the sausage shall be stuffed in casings or cloth bags

not exceeding 3⅓ inches in diameter, measured at the time of stuffing. After being stuffed, the sausage shall be held in a drying room at a temperature not lower than 45 °F. for the remainder of a 35-day period, measured from the time the curing materials are added to the meat. At any time after stuffing, if the establishment operator deems it desirable, the product may be heated in a water bath for a period not to exceed 3 hours at a temperature not lower than 85 °F., or subjected to smoking at a temperature not lower than 80 °F., or the product may be both heated and smoked as specified. The time consumed in heating and smoking, however, shall be in addition to the 35-day holding period specified.

Method No. 5. The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3⅓ pounds of salt to each hundredweight of the unstuffed sausage shall be thoroughly mixed with the ground or chopped meat. After being stuffed, the sausage shall be held for not less than 65 days at a temperature not lower than 45 °F. The coverings for sausage prepared according to this method may be coated at any stage of the preparation before or during the holding period with paraffin or other substance approved by the Administrator.

Method No. 6. (A) *Basic requirements.* The meat shall be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3.33 pounds of salt to each hundredweight of the unstuffed sausage, excluding the weight of dry ingredients, shall be thoroughly mixed with the ground or chopped meat. After the curing mixture has been added, the sausage shall be held for two time periods, a holding period and a drying period. The holding period will be for a minimum of 48 hours at a room temperature not lower than 35 ° F. This holding period requirement may be fulfilled totally or in part before the drying period and then the remainder, if any, after the drying period or as an extension of the drying period. During the drying period, the sausage shall be held in a drying room at a temperature not lower than 50 (10.0 ° F. (10.0 ° C) for a period of time determined by Tables 3A, 3B, and 4. The length of the drying period, established in (c)(3)(i)(A), may be modified as provided in paragraphs (c)(3)(i)(B) and (c)(3)(i)(C) of this section.

TABLE 3A—SAUSAGE DRYING ROOM TIMES BY METHOD NO. 6

Diameter of casing at time of stuffing[1]	Days in drying room[2]
Up to:	
1 inches	14
1½ inches	15
2 inches	16
2½ inches	18
3 inches	20
3½ inches	23
4 inches	25
4½ inches	30
5 inches	35
5½ inches	43
6 inches	50

[1] The drying room times for flattened or oval sausages shall use a diameter derived by measuring the circumference and dividing by 3.14 (pi).

[2] Drying room time may be modified as set forth in Tables 3B and 4.

(B) *Reduction in Drying Room Time.* During the holding period, the sausage may be smoked or fermented. If the temperature is increased to 70 ° F. (21.1 ° C) or higher, while the sausage is being held after adding curing materials but before the drying period, the subsequent drying room times prescribed for this method may be reduced according to the schedule in Table 3B. No interpolation of values is permissible.

TABLE 3B—PERCENTAGE REDUCTION IN DRYING ROOM TIME (TABLE 3A) PERMITTED BY HOLDING TIMES AND TEMPERATURES PRIOR TO DRYING [1]

Minimum Time	Minimum Temperature [2]									
	70 ° F	75 ° F	80 ° F	85 ° F	90 ° F	95 ° F	100 ° F	105 ° F	110 ° F	120 ° F
	21.1 ° C	23.9 ° C	26.7 ° C	29.5 ° C	32.2 ° C	35.0 ° C	37.9 ° C	40.6 ° C	43.3 ° C	48.9 ° C
24 hours	4	5	8	10	15	23	37	57	90	[3]100
48 hours	9	12	18	25	35	49	88	[3]100	[3]100	100
72 hours	14	19	28	39	55	74	[3]100	100	100	100
96 hours	19	26	38	53	75	98	100	100	100	100
120 hours	24	33	48	67	95	[3]100	100	100	100	100

[1] In computing the days to be deducted, the number with any fraction shall be rounded to the next lower whole number and shall be deducted from the required total drying time. Example: Sausage stuffed in 3″ diameter casing requires 20 days in the drying room (from Drying Room Times, Table 3A). If allowed to ferment, after addition of curing materials, at 80 ° F. for 48 hours, the 20 day drying time may be reduced 18% (from Table 3B). Eighteen percent of 20 day equals 3.6 days. Twenty days minus 3 days equals 17 days. The total drying time required in the drying room, therefore, will be 17 days.

[2] Either room temperature or internal product temperature shall be used for sausages that will be subsequently dried to a moisture-protein ratio of 2.3:1 or less. Internal product temperature shall be used for all other sausages.
[3] Trichinae will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for products so treated.

(C) *Reduced Salt Content—Drying Room Times.* Salt content of less than 3.33 pounds for each hundredweight of sausage formulation, excluding dry ingredients, (such as salts, sugars, and spices), may be permitted provided the drying time is increased according to the schedule contained in Table 4.

TRICHINA TREATMENT OF SAUSAGE BY METHOD NO. 6;

TABLE 4—REDUCED SALT CONTENT—DRYING ROOM TIMES

[Required percentage increase in drying room time (table 3A) for added salt of less than 3.33 pounds per hundredweight of sausage]

Minimum pounds of salt added to sausage [1]	Increase in drying room time [2]
3.3	1
3.2	4
3.1	7
3.0	10
2.9	13
2.8	16
2.7	19
2.6	22
2.5	25
2.4	28
2.3	31
2.2	34
2.1	37
2.0	40

[1] Calculate the salt content for column 1 as follows: Multiply the pounds of salt in the sausage formulation by 100. Then divide this number by the total weight of sausage formulation minus the weight of dry ingredients and round down to the next lowest 0.1%. Percents may be substituted for pounds.

Example: 120 lbs. pork, 3.56 lbs. salt, 2 lbs. spices, 0.5 lbs. wine, 1 lb. water and starter culture, 0.8 lbs. sugar, .012 lbs. sodium nitrite total weight is 127.872 lbs.

$(3.56\times100)/(127.872-3.56-2-.8-.012)=356/121.5=2.93$

Therefore, the sausage drying time must be increased by 13 percent.

[2] In computing the days to be added to the required total drying time, fractions shall be rounded to the next higher whole number and added to the required total drying time. Example: Sausage stuffed in 3½ inch diameter casing requires 23 days in the drying room (from Drying Room Times). If the quantity of salt added per hundredweight of sausage is 2 pounds instead of 3.33 pounds, the drying room time must be increased by 40 percent (from Reduced Salt Content-Drying Room Times), or 9.2 days. The 9.2 is rounded up to 10 days and is added to the 23 days to equal 33 days. The total drying time required in the drying room, therefore, will be 33 days.

Method No. 7, Dry Sausages. (A) *General Requirements.* The establishment shall use meat particles reduced in size to no more than 1/4 inch in diameter. The establishment shall add a curing mixture containing no less than 2.7 pounds of salt per hundred pounds of meat and mix it uniformly throughout the product. The establishment shall hold, heat, and dry the product according to paragraph (B) or (C) below.

(B) *Holding, Heating, and Drying Treatment, Large Sausages.* Except as permitted in (C) below, the establishment shall subject sausages in casings not exceeding 105 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

TREATMENT SCHEDULE FOR SAUSAGES 105 MILLIMETERS (4⅛ INCHES) OR LESS IN DIAMETER

Minimum chamber temperature		Minimum time (hours)
(°F)	(°C)	
50	10	12
90	32.2	1
100	37.8	1
110	43.3	1
120	48.9	1
125	51.7	7

Following the preceding treatment, the establishment shall dry the sausages at a temperature not lower than 50 °F (10 °C) for not less than 7 days.

(C) *Heating and Drying Treatment, Small Sausages.* Alternatively, the establishment may subject sausages in casings not exceeding 55 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

TREATMENT SCHEDULE FOR SAUSAGES 55 MILLIMETERS (2⅛ INCHES) OR LESS IN DIAMETER

Minimum chamber temperature		Minimum time (hours)
(°F)	(°C)	
50	10	12
100	37.8	1
125	51.7	6

Following the preceding heat treatment, the establishment shall dry the sausages at a temperature not lower than 50 °F (10 °C) for not less than 4 days.

(ii) *Capocollo (capicola, capacola).* Boneless pork butts for capocollo shall be cured in a dry-curing mixture containing not less than 4½ pounds of salt per hundredweight of meat for a period of not less than 25 days at a temperature not lower than 36 °F. If the curing materials are applied to the butts by the process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled according to any of the

usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts shall not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed. After being stuffed, the product shall be smoked for a period of not less than 30 hours at a temperature not lower than 80 °F., and shall finally be held in a drying room not less than 20 days at a temperature not lower than 45 °F.

(iii) *Coppa.* Boneless pork butts for coppa shall be cured in a dry-curing mixture containing not less than 4½ pounds of salt per hundredweight of meat for a period of not less than 18 days at a temperature not lower than 36 °F. If the curing mixture is applied to the butts by the process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled according to any of the usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts shall not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed. After being stuffed, the product shall be held in a drying room not less than 35 days at a temperature not lower than 45 °F.

(iv) *Hams and pork shoulder picnics.* In the curing of hams and pork shoulder picnics, one of the methods below shall be used. For calculating days per pound, the establishment shall use the weight of the heaviest ham or picnic in the lot.

Method No. 1. The hams and pork shoulder picnics shall be cured by a dry-salt curing process not less than 40 days at a temperature no lower than 36 °F. The products shall be laid down in salt, not less than 4 pounds to each hundredweight of product, the salt being applied in a thorough manner to the lean meat of each item. When placed in cure, the products may be pumped with pickle if desired. At least once during the curing process, the products shall be overhauled (turned over for the application of additional cure) and additional salt applied, if necessary, so that the lean meat of each item is thoroughly covered. After removal from cure, the products may be soaked in water at a temperature not higher than 70 °F for not more than 15 hours, during which time the water may be changed once, but they shall not be subjected to any other treatment designed to remove salt from the meat except that superficial washing may be allowed. The products shall finally be dried or smoked at a time and temperature not less than a combination prescribed in Table 5 of Method No. 3.

Method No. 2. [Reserved]

Method No. 3. (A) *Curing.* (Other than bag curing): Establishments shall cure hams and shoulders by using a cure mixture containing not less than 70 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Total curing time consists of a mandatory cure contact time and an optional equalization time.

(B) *Cure Contact Time.* This is the cure contact period, during which the establishment shall keep exposed muscle tissue coated with the cure mixture at least 28 days but for no less than 1.5 days per pound of ham or shoulder. Overhaul is optional so long as the exposed muscle tissue remains coated with curing mixture.

(C) *Equalization.* The establishment may provide an equalization period after the minimum cure contact period in (B) above to permit the absorbed salt to permeate the product's inner tissues. Equalization is the time after the excess cure has been removed from the product at the end of the cure contact period until the product is placed in the drying room and the drying period begins. The total curing time (equalization plus cure contact) shall be at least 40 days and in no case less than 2 days per pound of an uncured ham or shoulder.

(D) *Removing Excess Cure.* After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.

(E) *Bag Curing.* Bag curing is a traditional ham curing technique in which the manufacturer wraps the ham and all of the cure mixture together in kraft paper then hangs them individually. The paper keeps the extra cure mixture in close contact with the product making reapplication of salt unnecessary, and it protects the product from mites and insects. Establishments may employ the bag curing method as an alternative to (A) through (D) above. An establishment which elects to use the bag curing method shall apply a cure mixture containing at least 6 pounds of salt per 100 pounds of uncured product. The establishment shall rub the curing mixture into the exposed muscle tissue, pack the hock region with the curing mixture, and use uncoated wrapping paper to wrap the product together with any remaining curing mixture. The bag cured product shall remain wrapped throughout the curing period and may or may not remain wrapped during the drying period. In any case, the curing period shall be at least 40 days but not less than 2 days per pound of an uncured

ham or shoulder. After curing, the cured product shall be exposed to a drying time and temperature prescribed in Table 5.

(F) *Curing Temperature.* During the curing period the establishment shall use one of the following procedures:

(1) The establishment shall control the room temperature at not less than 35 ° F (1.7 ° C) nor greater than 45 ° F (7.2 ° C) for the first 1.5 days per pound of an uncured ham or shoulder, and not less than 35 ° F (1.7 ° C) nor greater than 60 ° F (15.6 ° C) for the remainder of the curing period.

(2) The establishment shall monitor and record daily product temperature. The room temperature need not be controlled but days on which the product temperature drops below 35 ° F (1.7 ° C) shall not be counted as curing time. If the product temperature exceeds 45 ° F (7.2 ° C) within the first period of 1.5 days per pound of an uncured ham or shoulder or if it exceeds 60 ° F (15.6 ° C) for the remainder of the curing period, the establishment shall cool the product back to the 45 ° F (7.2 ° C) maximum during the first period or 55 ° F (12.8 ° C) maximum during the remainder of the period.

(3) The establishment shall begin curing product only between the dates of December 1 and February 13. The room temperature need not be controlled, but the establishment shall monitor and record daily room temperatures, and days in which the room temperature drops below 35 ° F (1.7 ° C) shall not be counted as curing time.

(G) *Drying.* After the curing period, establishments shall use one of three procedures for drying:

(1) The establishment shall subject the product to a controlled room temperature for a minimum time and minimum temperature combination prescribed in Table 5 or for a set of such combinations in which the total of the fractional periods (in column 4 of Table 5) exceeds 1.5.

(2) Establishments using uncontrolled room temperatures shall monitor and record the internal product temperature. The drying period shall be complete when, from the days which can be counted as curing time, one of the time/temperature combinations of Table 5 is satisfied or when the total of the fractional values for the combinations exceeds 1.5.

(3) Establishments using uncontrolled room temperatures shall dry the product for a minimum of 160 days including the entire months of June, July, and August. This procedure is obviously dependent on local climatic conditions and no problem exists with respect to current producers who use this procedure. Future applicants shall demonstrate that their local monthly average temperatures and the local monthly minimum temperatures are equal to or warmer than the normal average temperatures and normal minimum temperatures compiled by the National Oceanic and Atmospheric Administration for Boone, North Carolina, station 31–0977, 1951 through 1980.

MONTHLY TEMPERATURES (° F) FOR BOONE NC, 1951–1980

Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sep.
Normal average temperatures								
32.2	34.1	41.3	51.2	59.1	65.1	68.3	67.5	61.6
Normal minimum temperatures								
22.8	24.2	30.8	39.6	48.1	54.7	58.5	57.6	51.6

Drying Times and Temperatures for Trichina Inactivation in Hams and Shoulders

TABLE 5.—MINIMUM DRYING DAYS AT A MINIMUM TEMPERATURE*

Minimum Drying Temperature		Minimum days at drying temperature	Fractional period for one day of drying
Degrees fahrenheit	Degrees centigrade		
130	54.4	1.5	.67
125	51.7	2	.50
120	48.9	3	.33
115	46.1	4	.25
110	43.3	5	.20
105	40.6	6	.17
100	37.8	7	.14

TABLE 5.—MINIMUM DRYING DAYS AT A MINIMUM TEMPERATURE*—Continued

Minimum Drying Temperature		Minimum days at drying temperature	Fractional period for one day of drying
Degrees fahrenheit	Degrees centigrade		
95	35.0	9	.11
90	32.2	11	.091
85	29.4	18	.056
80	26.7	25	.040
75	23.9	35	.029

*Interpolation of these times or temperatures is not acceptable; establishments wishing to use temperatures or times not in this Table shall first validate their efficacy as provided by 318.10(c)(4) of this section.

Method No. 4.

(A) Cure: Establishments shall cure hams and shoulders by using a cure mixture containing not less than 71.5 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Establishments may substitute potassium chloride (KCl) for up to half of the required salt on an equal weight basis.

(B) *Curing.* Establishments shall apply the cure at a rate not less than 5.72 pounds of salt and KCl per hundred pounds of fresh meat. The cure shall be applied in either three or four approximately equal amounts (two or three overhauls) at separate times during the first 14 days of curing.

(C) *Cure Contact Time.* Establishments shall keep the product in contact with the cure mixture for no less than 2 days per pound of an uncured ham or shoulder but for at least 30 days. Establishments shall maintain the curing temperature at no less than 35° F (1.7° C) during the cure contact time.

(D) *Equalization.* After the cure contact period, establishments shall provide an added equalization period of no less than 1 day per pound of an uncured ham or shoulder but at least 14 days. Equalization is the time after the excess cure has been removed from the product, the end of the cure contact period, and before the drying period begins. Establishments may substitute additional cure contact days for an equal number of equalization days.

(E) *Removing Excess Cure.* After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.

(F) *Drying.* After the curing period, establishments shall use one of the controlled temperature methods for drying listed in Method No. 3 of this subparagraph.

Method No. 5

(A) *Curing.* The establishment shall cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations.

Percent brine=100×[salt]/([salt]+[water])

The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration in the ham.

(B) *Drying and Total Process Times.* The establishment shall dry the cured ham at a minimum temperature of 55 °F (13 °C) for at least 150 days. The total time of drying plus curing shall be at least 206 days.

(C) *Ensuring an Acceptable Internal Brine Concentration.* (1) To establish compliance, the establishment shall take product samples from the first 12 lots of production as follows: From each lot,

(i) One sample shall be taken from each of 5 or more hams;

(ii) Each sample shall be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency shall consider other method(s) of sampling the dry-cured hams to determine the minimum internal brine concentration, as long as the establishment proposes it and submits data and other information to establish its sufficiency to the Director of the Processed Products Inspection Division;

(iii) Each sample shall weigh no less than 100 grams;

(iv) The samples shall be combined as one composite sample and sealed in a water vapor proof container;

(v) The composite sample shall be submitted to a laboratory accredited under the provisions of §318.21 to be analyzed for salt and water content using methods from the ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC),'' 15th Edition, 1990, Section 983.18 (page 931) and Section 971.19 (page 933) which are incorporated by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists, suite 400–BW, 2200 Wilson Boulevard, Arlington, VA 22201–3301. Copies may be inspected at the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment shall freeze the composite sample immediately after the samples are combined;

(vi) Once the laboratory results for the composite sample are received, the manufacturer shall calculate the internal brine concentration by multiplying the salt concentration by 100 and then dividing that figure by the sum of the salt and water concentrations;

(vii) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance shall be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested shall be held until the establishment brings the lot into compliance by further processing.

(2) To maintain compliance, the establishment shall take samples, have the samples analyzed, and perform the brine calculations

as set forth above from one lot every 13 weeks. Lots being tested to maintain compliance shall not be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested to maintain compliance, the establishment shall develop and propose steps acceptable to FSIS to ensure that the process is corrected.

(3) Accredited laboratory results and the brine calculations shall be placed on file at the establishment and available to Program employees for review.

Method No. 6

(A) *Curing.* The establishment shall cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations.

Percent brine = 100 × [salt] / ([salt] + [water])

The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration.

(B) *Drying and Total Process Times.* The establishment shall dry the cured ham at a minimum temperature of 110 ° F (43 ° C) for at least 4 days. The total time of drying plus curing shall be at least 34 days.

(c) *Ensuring an Acceptable Internal Brine Concentration.*

(1) To establish compliance the establishment shall take product samples from the first 12 lots of production as follows: From each lot,

(i) One sample shall be taken from each of 5 or more hams;

(ii) Each sample shall be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency will consider other methods of sampling the dry-cured hams to determine internal brine concentration, as long as the establishment proposes it and submits data and other information to establish its sufficiency to the Director of the Processed Products Inspection Division;

(iii) Each sample shall weigh no less than 100 grams;

(iv) The samples shall be combined as one composite sample and sealed in a water vapor proof container;

(v) The composite sample shall be submitted to a laboratory accredited under the provisions of §318.21 to be analyzed for salt and water content using methods from the ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC),'' 15th Edition, 1990, section 983.18 (page 931) and section 971.19 (page 933) which are incorporated by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists, suite 400–BW, 2200 Wilson Boulevard, Arlington, VA 22201–3301. Copies may be inspected at the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment shall freeze the composite sample immediately after the samples are combined;

(vi) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance shall be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested shall be held until the establishment brings the lot into compliance by further processing.

(2) To maintain compliance, the establishment shall take samples, have the samples analyzed, and perform the brine calculations as set forth above from one lot every 13 weeks. Lots being tested to maintain compliance shall not be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested to maintain compliance, the establishment shall develop and propose steps acceptable to FSIS to ensure that the process is corrected.

(3) Accredited laboratory results and the brine calculations shall be placed on file in the establishment and available to Program employees for review.

(v) *Boneless pork loins and loin ends.* In lieu of heating or refrigerating to destroy possible live trichinae in boneless loins, the loins may be cured for a period of not less than 25 days at a temperature not lower than 36 °F. by the use of one of the following methods:

Method No. 1. Application of a dry-salt curing mixture containing not less than 5 pounds of salt to each hundredweight of meats.

Method No. 2. Application of a pickle solution of not less than 80° strength (salometer) on the basis of not less than 60 pounds of pickle to each hundredweight of meat.

Method No. 3. Application of a pickle solution added to the dry-salt cure prescribed as Method No. 1 in this subdivision (v) provided the pickle solution is not less than 80° strength (salometer).

After removal from cure, the loins may be soaked in water for not more than 1 hour at a temperature not higher than 70 °F. or washed under a spray but shall not be subjected, during or after the curing process, to

any other treatment designed to remove salt.

Following curing, the loins shall be smoked for not less than 12 hours. The minimum temperature of the smokehouse during this period at no time shall be lower than 100 °F., and for 4 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 125 °F.

Finally, the product shall be held in a drying room for a period of not less than 12 days at a temperature not lower than 45 °F.

(4) The Administrator shall consider additional processing methods upon petition by manufacturers, and shall approve any such method upon his/her determination that it can be properly monitored by an inspector and that the safety of such methods is adequately documented by data which has been developed by following an experimental protocol previously reviewed and accepted by the Department.

(d) General instructions: When necessary to comply with the requirements of this section, the smokehouses, drying rooms, and other compartments used in the treatment of pork to destroy possible live trichinae shall be suitably equipped, by the operator of the official establishment, with accurate automatic recording thermometers. Circuit supervisors are authorized to approve for use in sausage smokehouses, drying rooms, and other compartments, such automatic recording thermometers as are found to give satisfactory service and to disapprove and require discontinuance of use, for purposes of the regulations in this subchapter, any thermometers (including any automatic recording thermometers) of the establishment that are found to be inaccurate or unreliable.

(e) The requirements for using the pooled sample digestion technique to analyze pork for the presence of trichina cysts are:

(1) The establishment shall submit for the approval of the Regional Director its proposed procedure for identifying and pooling carcasses, collecting and pooling samples, testing samples (including the name and address of the laboratory), communicating test results, retesting individual carcasses, and maintaining positive identification and clear separation of pork found to be trichina-free from untested pork or trichina-positive pork.

(2) The establishment shall use the services of a laboratory approved by the Administrator for all required testing. Such approval shall be based on adequacy of facilities, reagents, and equipment, and on demonstration of continuing competency and reliability in performing the pooled sample digestion technique for trichinae.

(3) The establishment shall sample no less than 5 grams of diaphragm muscle or tongue tissue from each carcass or no less than 10 grams of other muscle tissue. Samples may be pooled but a pool shall not consist of more than 100 grams of sample. Sampling and sample preparation are subject to inspection supervision.

(4) Pork or products made from tested pork shall not be released as trichina free from the official establishment without treatment until the inspector in charge receives a laboratory report that the tested pork is free of trichina cysts.

(f) *Approval of other tests for trichinosis in pork.* The Administrator shall consider any additional analytical method for trichinosis upon petition by a manufacturer, and may approve that method upon the determination that it will detect at least 98 percent of swine bearing cysts present at a tissue density equal to or less than one cyst per gram of muscle from the diaphragm pillars at a 95 percent confidence level. Any such petitions shall be supported by any data and other information that the Administrator finds necessary. Notice of any approval shall be given in the FEDERAL REGISTER, and the approved method will be incorporated into this section.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 31517; Nov. 15, 1973; 39 FR 40580, Nov. 19, 1974; 50 FR 5229, Feb. 7, 1985; 50 FR 48075, Nov. 21, 1985; 52 FR 12517, Apr. 17, 1987; 57 FR 27874, June 22, 1992; 57 FR 33633, July 30, 1992; 57 FR 56440, Nov. 30, 1992]

§ 318.11 [Reserved]

§ 318.12 Manufacture of dog food or similar uninspected article at official establishments.

(a) When dog food, or similar uninspected article is manufactured in an edible product department, there shall be sufficient space allotted and adequate equipment provided so that

the manufacture of the uninspected article in no way interferes with the handling or preparation of edible products. Where necessary to avoid adulteration of edible products, separate equipment shall be provided for the uninspected article. To assure the maintenance of sanitary conditions in the edible product departments, the operations incident to the manufacture of the uninspected article will be subject to the same sanitary requirements that apply to all operations in edible product departments. The manufacture of the uninspected article shall be limited to those hours during which the establishment operates under inspectional supervision; and there shall be no handling, other than receiving at the official establishment, of any of the product ingredient of the uninspected article, other than during the regular hours of inspection. The materials used in the manufacture of the uninspected article shall not be used so as to interfere with the inspection of edible product or the maintenance of sanitary conditions in the department or render any edible product adulterated. The meat, meat byproducts, and meat food product ingredients of the uninspected article may be admitted into any edible products department of an official establishment only if they are U.S. Inspected and Passed. Products within §314.11 of this subchapter or parts of carcasses of kinds not permitted under the regulations in this subchapter to be prepared for human food (e.g., lungs or intestines), which are produced at any official establishment, may be brought into the inedible products department of any official establishment for use in uninspected articles under this section. The uninspected article may be stored in, and distributed from, edible product departments: *Provided,* That adequate facilities are furnished, there is no interference with the maintenance of sanitary conditions, and such article is properly identified.

(b) When dog food or similar uninspected article is manufactured in a part of an official establishment other than an edible product department, the area in which the article is manufactured shall be separated from edible product departments in the manner required for separation between edible product departments and inedible product departments. Sufficient space must be allotted and adequate equipment provided so that the manufacture of the uninspected article does not interfere with the proper functioning of the other operations at the establishment. Except as provided in §314.11 of this subchapter, nothing in this paragraph shall be construed as permitting any deviation from the requirement that dead animals, condemned products, and similar materials of whatever origin, must be placed in the inedible product rendering equipment, and without undue delay. The manufacture of the uninspected article must be such as not to interfere with the maintenance of general sanitary conditions on the premises, and it shall be subject to inspectional supervision similar to that exercised over other inedible product departments. There shall be no movement of any product from an inedible product department to any edible product department. Trucks, barrels, and other equipment shall be cleaned before being returned to edible product departments from inedible product departments. Unoffensive material prepared outside edible product departments may be stored in, and distributed from, edible product departments only if packaged in clean, properly identified, sealed containers.

(c) Animal food shall be distinguished from articles of human food, so as to avoid distribution of such animal food as human food. To accomplish this, such animal food shall be labeled or otherwise identified in accordance with §325.11(d) of this subchapter.

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 53 FR 24679, June 30, 1988]

§ 318.13 Mixtures containing product but not amendable to the Act.

Mixtures containing product but not classed as a meat food product under the Act shall not bear the inspection legend or any abbreviation or representation thereof unless manufactured under the food inspection service provided for in part 350 of subchapter B of this chapter. When such mixtures are manufactured in any part of an official establishment, the sanitation of that part of the establishment shall be supervised by Program employees, and

the manufacture of such mixtures shall not cause any deviation from the requirement of § 318.1.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973]

§ 318.14 Adulteration of product by polluted water; procedure for handling.

(a) In the event there is polluted water (including but not limited to flood water) in an official establishment, all products and ingredients for use in the preparation of such products that have been rendered adulterated by the water shall be condemned.

(b) After the polluted water has receded from an official establishment, all walls, ceilings, posts, and floors of the rooms and compartments involved, including the equipment therein, shall, under the supervision of an inspector, be cleaned thoroughly by the official establishment personnel. An adequate supply of hot water under pressure is essential to make such cleaning effective. After cleaning, a solution of sodium hypochlorite containing approximately one-half of 1 percent available chlorine (5,000 p/m) or other equivalent disinfectant approved by the Administrator[1] shall be applied to the surface of the rooms and equipment and rinsed with potable water before use.

(c) Hermetically sealed containers of product which have been contaminated by polluted water shall be examined promptly by the official establishment under supervision of an inspector and rehandled as follows:

(1) Separate and condemn all product in damaged or extensively rusted containers.

(2) Remove paper labels and wash the remaining containers in warm soapy water, using a brush where necessary to remove rust or other foreign material. Disinfect these containers by either of the following methods:

(i) Immerse in a solution of sodium hypochlorite containing not less than 100 p/m of available chlorine or other equivalent disinfectant approved by the Administrator,[1] rinse in potable water, and dry thoroughly; or

(ii) Immerse in 212 °F. water, bring temperature of the water back to 212 °F. and maintain the temperature at 212 °F. for 5 minutes, then remove containers from water and cool them to 95 °F. and dry thoroughly.

(3) After handling as described in paragraph (c)(2) of this section, the containers may be relacquered, if necessary, and then relabeled with approved labels applicable to the product therein.

(4) The identity of the canned product shall be maintained throughout all stages of the rehandling operations to insure correct labeling of the containers.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 34455, Dec. 14, 1973]

§ 318.15 Tagging chemicals, preservatives, cereals, spices, etc., "U.S. retained."

When any chemical, preservative, cereal, spice, or other substance is intended for use in an official establishment, it shall be examined by a Program employee and if found to be unfit or otherwise unacceptable for the use intended, or if final decision regarding acceptance is deferred pending laboratory or other examination, the employee shall attach a ''U.S. retained'' tag to the substance or container thereof. The substance so tagged shall be kept separate from other substances as the circuit supervisor may require and shall not be used until the tag is removed, and such removal shall be made only by a Program employee after a finding that the substance can be accepted, or, in the case of an unacceptable substance, when it is removed from the establishment.

§ 318.16 Pesticide chemicals and other residues in products.

(a) *Nonmeat ingredients.* Residues of pesticide chemicals, food additives and color additives or other substances in or on ingredients (other than meat, meat byproducts, and meat food products) used in the formulation of products shall not exceed the levels permitted under the Federal Food, Drug, and Cosmetic Act, and such nonmeat

[1] A list of approved disinfectants is available upon request to Scientific Services, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

ingredients must otherwise be in compliance with the requirements under that Act.

(b) *Products, and meat, meat byproduct, or other meat food product ingredients.* Products, and products used as ingredients of products, shall not bear or contain any pesticide chemical, food additives, or color additive residue in excess of the level permitted under the Federal Food, Drug, and Cosmetic Act and the regulations in this subchapter, or any other substance that is prohibited by such regulations or that otherwise makes the products adulterated.

(c) *Standards and procedures.* Instructions specifying the standards and procedures for determining when ingredients of finished products are in compliance with this section shall be issued to the inspectors by the Administrator. Copies of such instructions will be made available to interested persons upon request made to the Administrator.

§ 318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef.

(a) Cooked beef and roast beef, including sectioned and formed roasts and chunked and formed roasts, and cooked corned beef shall be prepared by one of the time and temperature combinations in the following table. The stated temperature is the minimum which shall be produced and maintained in all parts of each piece of meat for at least the stated time:

TABLE FOR TIME/TEMPERATURE COMBINATION FOR COOKED BEEF, ROAST BEEF, AND COOKED CORNED BEEF

Minimum internal temperature		Minimum processing time in minutes after minimum temperature is reached
Degrees Fahrenheit	Degrees Centigrade	
130	54.4	121
131	55.0	97
132	55.6	77
133	56.1	62
134	56.7	47
135	57.2	37
136	57.8	32
137	58.4	24
138	58.9	19
139	59.5	15
140	60.0	12
141	60.6	10
142	61.1	8
143	61.7	6
144	62.2	5
145	62.8	Instantly

TABLE FOR TIME/TEMPERATURE COMBINATION FOR COOKED BEEF, ROAST BEEF, AND COOKED CORNED BEEF—Continued

(b) Cooked beef, including sectioned and formed roasts and chunked and formed roasts, and cooked corned beef shall be moist cooked throughout the process or, in the case of roast beef or corned beef to be roasted, cooked as provided in paragraph (c) of this section. The moist cooking may be accomplished by (1) placing the meat in a sealed, moisture impermeable bag, removing the excess air, and cooking, (2) completely immersing the meat, unbagged, in water throughout the entire cooking process, or (3) using a sealed oven or steam injection to raise the relative humidity above 90 percent throughout the cooking process.

(c) Roast beef or corned beef to be roasted shall be cooked by one of the following methods:

(1) Heating roasts of 10 pounds or more in an oven maintained at 250 °F (121 °C) or higher throughout the process;

(2) Heating roasts of any size to a minimum internal temperature of 145 °F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour; or

(3) Heating roasts of any size in an oven maintained at any temperature that will satisfy the internal temperature and time requirements of paragraph (a) of this section if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour.

The relative humidity may be achieved by use of steam injection or by sealed ovens capable of producing

and maintaining the required relative humidity.

(d)(1) Except as provided in paragraph (d)(2) of this section, establishments producing cooked beef, roast beef, or cooked corned beef shall have sufficient monitoring equipment, including recording devices, to assure that the time (within 1 minute), the temperature (within 1 °F), and relative humidity (within 5 percent) limits of these processes are being met. Data from the recording devices shall be made available to a program employee upon request.

(2) In lieu of recording devices, establishments may propose in the written procedures prescribed in paragraph (f) of this section, an alternative means of providing inspection personnel with evidence that finished product has been prepared in compliance with the humidity requirements of paragraphs (b) and (c) of this section, and the 145 °F (62.8 °C) temperature requirements of paragraph (a) of this section.

(e) Each package of finished product shall be plainly and permanently marked on the immediate container with the date of production either in code or with the calendar date.

(f) In order to assure that cooked beef, roast beef, and cooked corned beef are handled, processed, and stored under sanitary conditions, the establishment shall submit a set of written procedures through the inspector-in-charge for approval by the Regional Director. The written procedures shall include the following information:

(1) The temperature to which raw frozen product is thawed and the time required.

(2) The lot identification procedure for lots of product during processing.

(3) The storage time and temperature combinations which the establishment intends to use before cooking, the cooking time and temperature the establishment intends to use, and the time, if any, the establishment intends to wait after cooking and before cooling.

(4) If a code, instead of the calendar date, is used on the immediate container of the finished product, its meaning shall also be included.

(5) Any other critical control points in the procedures which could affect the safety of the product.

(6) In lieu of recording devices, the alternate means permitted by § 318.17(d)(2) of providing evidence to inspection personnel that the finished product will be prepared in compliance with temperature or humidity requirements.

(7) Any other alternate procedure used that is permitted in this section.

(g) The establishment shall maintain records and reports which document the time, temperature, and humidity at which any cooked beef, roast beef, or cooked corned beef is cooked and cooled at the establishment. Such records shall be kept by the establishment for 6 months or for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records. Such records shall be made available to the inspector or any duly authorized representative of the Secretary upon request.

(h) The handling and processing of cooked beef, roast beef, and cooked corned beef before, during, and after cooking shall be such as to prevent the finished product from being adulterated. As a minimum, they shall be controled as follows:

(1) The establishment shall notify the inspector-in-charge which processing procedure will be used on each lot, including time and temperature.

(2) In order to assure uniform heat penetration and consequent adequate cooking of each piece of beef, individual pieces of raw product in any one lot shall either not vary in weight by more than 2 pounds or not vary in thickness by more than 2 inches at the thickest part. Alternate methods of assuring uniform heat penetration may be submitted in writing for approval to the Regional Director.

(3) A water-based solution that is used for injecting or immersing the meat shall be refrigerated to 50 °F (10 °C) or lower from the time it contacts the meat, and shall be filtered each time it is recirculated or reused.

(4) A nonmeat ingredient, including the water-based solution in (h)(3) above, which has contacted meat shall

be discarded at the end of that day's production unless it is in continuous contact with one batch of product.

(5) Product prepared for cooking shall be entered into the cooking cycle within 2 hours of completion of precooking preparation, or be placed immediately in a cooler at a temperature of 40 °F (4.4 °C) or lower.

(6) The time and temperature requirements shall be met before any product in the lot is removed from the cooking units. Unless otherwise specified in the written procedures approved in accordance with paragraph (f) of this section, the heat source shall not be shut off until these requirements are met.

(7) Other than incidental contact caused by water currents during immersion cooking or cooling, product shall be placed so that it does not touch or overlap other products. This provision does not apply to product that is stirred or agitated to assure uniform heat transfer.

(8) Temperature sensing devices shall be so placed that they monitor product in the coldest part of the cooking unit; and when an oven temperature is required by paragraph (c) of this section, the oven temperature shall also be monitored in the coldest part of the cooking unit.

(9) If a humidity sensing device is required in an oven, it shall be placed so that it measures humidity in either the oven chamber or at the exit vent.

(10) Chilling shall begin within 90 minutes after the cooking cycle is completed.

(i) All product shall be chilled from 120 °F (48.8 °C) to 55 °F (12.7 °C) in no more than 6 hours.

(ii) Chilling shall continue and the product shall not be packed for shipment until it has reached 40 °F (4.4 °C).

(11) Any establishment that has experienced a cooking process deviation during preparation of product may either reprocess the product completely, continue the heating to 145 °F (62.8 °C), or contact the Regional Director for a review of the process schedule for adequacy and, if needed, for a cooking schedule to finish that one batch of product.

(12) An establishment that has experienced a cooling deviation after the product has been cooked shall contact the Regional Director to determine the disposition of that retained product.

(i) Cooked beef, roast beef, and cooked corned beef shall be so handled as to assure that the product is not recontaminated by direct contact with raw product. To prevent direct contamination of the cooked product, establishments shall:

(1) Physically separate areas where raw product is handled from areas where exposed cooked product is handled, using a solid impervious floor to ceiling wall; or

(2) Handle raw and exposed cooked product at different times, with a cleaning of the entire area after the raw material handling is completed and prior to the handling of cooked product in that area; or

(3) Submit a written procedure for approval through the inspector-in-charge to the Circuit Supervisor detailing the steps to be taken which would avoid recontamination of cooked product by raw product during processing.

(j) To prevent indirect contamination of cooked product:

(1) Any work surface, machine, or tool which contacts raw product shall be thoroughly cleaned and sanitized with a solution germicidally equivalent to 50 ppm chlorine before it contacts cooked product;

(2) Employees shall wash their hands and sanitize them with a solution germicidally equivalent to 50 ppm chlorine whenever they enter the heat processed product area or before preparing to handle cooked product, and as frequently as necessary during operations to avoid product contamination; and

(3) Outer garments, including aprons, smocks, and gloves, shall be especially identified as restricted for use in cooked product areas only, changed at least daily, and hung in a designated location when the employee leaves the area.

(k) Cooked product shall not be stored in the same room as raw product unless it is first packaged in a sealed, water-tight container or is otherwise protected by a covering that has been

approved, upon written request, by the Circuit Supervisor.

(Approved by the Office of Management and Budget under control number 0583–0015)

[48 FR 24316, June 1, 1983]

§ 318.18 Handling of certain material for mechanical processing.

Material to be processed into ''Mechanically Separated (Species)'' shall be so processed within 1 hour from the time it is cut or separated from carcasses or parts of carcasses, except that such product may be held for no more than 72 hours at 40 °F. (4 °C.) or less, or held indefinitely at 0 °F. (−18 °C.) or less. ''Mechanically Separated (Species)'' shall, directly after being processed, be used as an ingredient in a meat food product except that it may be held prior to such use for no more than 72 hours at 40 °F. (4 °C.) or less or indefinitely at 0 °F. (−18 °C.) or less.

[43 FR 26423, June 20, 1978, as amended at 47 FR 28256, June 29, 1982]

§ 318.19 Compliance procedure for cured pork products.

(a) *Definitions.* For the purposes of this section:

(1) A *product* is that cured pork article which is contained within one *Group* as defined in paragraph (a)(2) of this section and which purports to meet the criteria for a single product designated under the heading ''Product Name and Qualifying Statements'' in the chart in § 319.104 or the chart in § 319.105.

(2) A *Product Group* or a *Group* means one of the following:

Group I, consisting of cured pork products which have been cooked while imperviously encased. Any product which fits into the Group will be placed in this Group regardless of any other considerations.

Group II, consisting of cured pork products which have been water cooked. Any product which does not fit into Group I but does fit into Group II will be placed into Group II regardless of any other considerations.

Group III, consisting of boneless smokehouse heated cured pork products. Any boneless product that does not fit into Group I or Group II shall be placed in Group III.

Group IV, consisting of bone-in or semi-boneless smokehouse heated cured pork products. Any product that is not completely boneless or still contains all the bone which is traditional for bone-in product, and does not fit into Group I, Group II, or Group III shall be placed in this Group.

(3) A *lot* is that product from one production shift.

(4) A *production rate* is frequency of production, expressed in days per week.

(5) *Protein fat free percentage, protein fat free content, PFF percentage, PFF content or PFF* of a product means the meat protein (indigenous to the raw, unprocessed pork cut) content expressed as a percent of the non-fat portion of the finished product.

(b) *Normal Compliance Procedures.* The Department shall collect samples of cured pork products and analyze them for their PFF content. Analyses shall be conducted in accordance with the ''Official Methods of Analysis of the Association of Official Analytical Chemists §§ 950.46, and 928.08 (Chapter 39).[1] The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Each analytical result shall be recorded and evaluated to determine whether future sampling of product Groups within an official establishment shall be periodic or daily under the provisions of paragraph (b)(1) of this section, and if the affected lot and subsequent production of like product shall be U.S. retained, or administratively detained, as appropriate, as provided in paragraph (b)(2) of this section.[2]

[1] A copy of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

[2] Rules for Rounding:

1. Laboratory results for percent meat protein and fat will be reported to the second decimal place (hundredths).

2. PFF and Sample Values for charting purposes will be calculated from the reported laboratory results to the second decimal place. Rounding of calculations to reach two decimal places will be done by the following rule:

Continued

(1) *Criteria to determine sampling frequency of Product Groups.* For each official plant preparing cured pork products, Product Groups shall be sampled periodically or daily. Analytical results shall be evaluated and the sampling frequency determined as follows:

(i) Determine the difference between the individual PFF analysis and the applicable minimum PFF percentage requirement of § 319.104 or § 319.105. The resulting figure shall be negative when the individual sample result is less than the applicable minimum PFF percentage requirement and shall be positive when the individual sample result is greater than the applicable minimum PFF percentage requirement.

(ii) Divide the resulting number by the standard deviation assigned to the Product Group represented by the sample to find the Standardized Difference. The standard deviation assigned to Groups I and II is 0.75 and to Groups III and IV is 0.91.

(iii) Add 0.25 to the Standardized Difference to find the Adjusted Standardized Difference.

(iv) Use the lesser of 1.90 and the Adjusted Standardized Difference as the Sample Value.

(v) Cumulatively total Sample Values to determine the Group Value. The first Sample Value in a Group shall be the Group Value, and each succeeding Group Value shall be determined by adding the most recent Sample Value to the existing Group Value; provided, however, that in no event shall the Group Value exceed 1.00. When calculation of a Group Value results in a figure greater than 1.00, the Group Value shall be 1.00 and all previous Sample Values shall be ignored in determining future Group Values.

(vi) The frequency of sampling of a Group shall be periodic when the Group Value is greater than −1.40 (e.g., −1.39, −1.14, 0, 0.50, etc.) and shall be daily when the Group Value is −1.40 or less (e.g., −1.40, −1.45, −1.50, etc.); provided, however, that once daily sampling has been initiated, it shall continue until the Group Value is 0.00 or greater, and each of the last seven Sample Values is −1.65 or greater (e.g., −1.63, −1.50, etc.), and there is no other product within the affected Group being U.S. retained as produced, under provisions of paragraph (b)(2) or (c).

(2) *Criteria for U.S. retention or administrative detention of cured pork products for further analysis.* Cured prok products shall be U.S. retained, or administratively detained, as appropriate, when prescribed by paragraphs (b)(2) (i) or (ii) of this section as follows:

(i) *Absolute Minimum PFF Requirement.* In the event that an analysis of an individual sample indicates a PFF content below the applicable minimum requirement of § 319.104 or § 319.105 by 2.3 or more percentage points for a Group I or II product, or 2.7 or more percentage points for a Group III or IV product, the lot from which the sample was collected shall be U.S. retained if in an official establishment and shall be subject to administrative detention if not in an official establishment unless returned to an official establishment and there U.S. retained. Any subsequently produced lots of like product and any lots of like product for which production dates cannot be established shall be U.S. retained or subject to administrative detention. Such administratively detained product shall be handled in accordance with part 329 of this subchapter, or shall be returned to an official establishment and subjected to the provisions of paragraph (c)(1) (i) or (ii) of this section, or shall be relabeled in compliance with the applicable standard, under the supervision of a program employee, at the expense of the product owner. Disposition of such

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All values of five-thousandths (0.005) or more will be rounded up to the next highest hundredth. All values of less than five-thousandths (0.005) will be dropped.

3. For compliance with the Absolute Minimum PFF requirements, the PFF will be rounded to the first decimal place (tenths). Rounding of calculations to reach one decimal place will be done by the following rule:

All PFF values of five-hundredths (0.05) or more will be rounded up to the next highest tenth. All PFF values of less than five-hundredths (0.05) will be dropped.

4. For product disposition (pass-fail of a minimum PFF standard for retained product) the average PFF calculation will be rounded to the first decimal place. Individual PFF Values will be calculated to the nearest hundredth as in (2) above. The average, however, will be rounded to the nearest tenth as in (3) above.

U.S. retained product shall be in accordance with paragraph (c) of this section.

(ii) *Product Value requirement.* The Department shall maintain, for each product prepared in an official establishment, a Product Value. Except as provided in paragraph (c)(2) of this section, calculation of the Product Value and its use to determine if a product shall be U.S. retained shall be as follows:

(A) Determine the difference between the individual PFF analysis and applicable minimum PFF percentage requirement of §319.104 and §319.105. The resulting figure shall be negative when the individual sample result is less than the applicable minimum PFF percentage requirement and shall be positive when the individual sample result is greater than the applicable minimum PFF percentage requirement.

(B) Divide the difference determined in paragraph (b)(2)(ii)(A) of this section by the standard deviation assigned to the product's Group in paragraph (b)(1)(ii) of this section to find the standardized difference.

(C) Use the lesser of 1.65 and the standardized difference as the Sample Value.

(D) Cumulatively total Sample Values to determine the Product Value. The first Sample Value of a product shall be the Product Value, and each succeeding Product Value shall be determined by adding the most recent Sample Value to the existing Product Value; provided, however, that in no event shall the Product Value exceed 1.15. When calculation of a Product Value results in a figure greater than 1.15, the Product Value shall be 1.15, and all previous Sample Values shall be ignored in determining future Product Values.

(E) Provided daily group sampling is in effect pursuant to the provisions of paragraph (b)(1) of this section, and provided further the Product Value is −1.65 or less (e.g., −1.66), the affected lot (if within the official establishment) and all subsequent lots of like product prepared by and still within the official establishment shall be U.S. retained and further evaluated under paragraph (c) of this section. Except for release of individual lot pursuant to paragraph (c)(1), subsequently produced lots of like product shall continue to be U.S. retained until discontinued pursuant to paragraph (c)(2) of this section.

(c) *Compliance procedure during product retention.* When a product lot is U.S. retained under the provisions of paragraph (b)(2) of this section, the Department shall collect three randomly selected samples from each such lot and analyze them individually for PFF content. The PFF content of the three samples shall be evaluated to determine disposition of the lot as provided in paragraph (c)(1) of this section and the action to be taken on subsequently produced lots of like product as provided in paragraph (c)(2) of this section.[3]

(1) A product lot which is U.S. retained under the provisions of paragraph (b)(2) of this section may be released for entry into commerce provided one of the following conditions is met:

(i) The average PFF content of the three samples randomly selected from the lot is equal to or greater than the applicable minimum PFF percentage required by §319.104 or §319.105. Further processing to remove moisture for the purpose of meeting this provision is permissible. In lieu of further analysis to determine the effects of such processing, each 0.37 percent weight reduction due to moisture loss resulting from the processing may be considered the equivalent of a 0.1 percent PFF gain.

(ii) The lot of the product is relabeled to conform to the provisions of §319.104 or §319.105, under the supervision of a program employee.

(iii) The lot is one that has been prepared subsequent to preparation of the lot which, under the provisions of paragraph (c)(2) of this section, resulted in discontinuance of U.S. retention of new lots of like product. Such lot may be released for entry into commerce prior

[3] If the processor does not wish to have the product evaluated in this manner, alternate sampling plans may be used provided such plans have been formulated by the processor and approved by the Administrator prior to evaluation by the three-sample criteria, and provided the analyses specified in such plans are performed at the expense of the processor.

to receipt of analytical results for which sampling has been conducted. Upon receipt of such results, they shall be subjected to the provisions of paragraphs (b)(2)(i) and (c)(2) of this section.

(2) The PFF content of three randomly selected samples from each U.S. retained lot shall be used to maintain the Product Value described in paragraph (c)(2)(ii). The manner and effect of such maintenance shall be as follows: (i) Find the average PFF content of the three samples.

(ii) Determine the difference between that average and the applicable minimum PFF percentage requirement of §319.104 or §319.105. The resulting figure shall be negative when the average of the sample results is less than the applicable minimum PFF percentage requirement and shall be positive when the average of the sample results is greater than the applicable minimum PFF requirements.

(iii) Divide the resulting figure by the standard deviation assigned to the product's Group in paragraph (b)(1)(ii) of this section, to find the standardized difference.

(iv) Use the lesser of 1.30 and the standardized difference as the Sample Value.

(v) Add the first Sample Value thus calculated to the latest Product Value calculated under the provisions of paragraph (c)(2)(ii) of this section to find the new Product Value. To find each succeeding Product Value, add the most recent Sample Value to the existing Product Value; provided, however, that in no event shall the Product Value exceed 1.15. When the addition of a Sample Value to an existing Product Value results in a figure greater than 1.15, the Product Value shall be 1.15 and all previous Sample Values shall be ignored in determining future Product Values.

(vi) New lots of like product shall continue to be retained pending disposition in accordance with paragraph (c)(1) of this section until, after 5 days of production, the Product Value is 0.00 or greater, and the PFF content of no individual sample from a U.S. retained lot is less than the Absolute Minimum PFF requirement specified in paragraph (b)(2)(i) of this section. Should an individual sample fail to meet its Absolute Minimum PFF requirement, the 5-day count shall begin anew.

(vii) When U.S. retention of new lots is discontinued under the above provisions, maintenance of the Product Value shall revert to the provisions of paragraph (b)(2)(ii) of this section.

(3) For purposes of this section, the plant owner or operator shall have the option of temporarily removing a product from its Product Group, provided product lots are being U.S. retained, as produced, and provided further that the average production rate of the product, over the 8-week period preceding the week in which the first U.S. retained lot was prepared, is not greater than 20 percent of the production rate of its Group. When a product is thus removed from its Group, analytical results of product samples shall not cause daily sampling of the Group. When pursuant to paragraph (c)(2)(vi) of this section, new lots of the product are no longer being U.S. retained, the product shall again be considered with its Group.

(d) *Adulterated and misbranded products.* Products not meeting specified PFF requirements, determined according to procedures set forth in this section, may be deemed adulterated under section 1(m)(8) of the Act (21 U.S.C. 601(m)(8)) and misbranded under section 1(n) of the Act (21 U.S.C. 601(n)).

(e) *Quality control.* Cured pork products bearing on their labeling the statement ''X% of Weight is Added Ingredients'' shall be prepared only under a quality control system or program in accordance with §318.4 of this subchapter. With respect to any other cured pork product, official establishments may institute quality control procedures under §318.4 of this subchapter. Cured pork products produced in such establishments may be exempt from the requirements of this section, provided inplant quality control procedures are shown to attain the same or higher degree of compliance as the procedures set forth in this section; provided, however, that all cured pork products produced shall be subject to the applicable Absolute Minimum PFF

content requirement, regardless of any quality control procedures in effect.

[49 FR 14877, Apr. 13, 1984; 49 FR 33434, Aug. 23, 1984, as amended at 59 FR 33642, June 30, 1994; 60 FR 10304, Feb. 24, 1995; 62 FR 45025, Aug. 25, 1997]

§ 318.20 Use of animal drugs.

Animal drug residues are permitted in meat and meat food products if such residues are from drugs which have been approved by the Food and Drug Administration and any such drug residues are within tolerance levels approved by the Food and Drug Administration, unless otherwise determined by the Administrator and listed herein.

[50 FR 32165, Aug. 9, 1985]

§ 318.21 Accreditation of chemistry laboratories.

(a) *Definitions—Accredited laboratory*—A non-Federal analytical laboratory that has met the requirements for accreditation specified in this section and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

Accreditation—Determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and part 381 of this chapter 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 product subject to regulations in this subchapter and part 381 of this chapter for the presence and amount of one of several classes of chemical residue, in accordance with the requirements of the Accredited Laboratory Program. Accreditations are granted separately for the food chemistry analysis of official samples and for the analysis of such samples for any one of the several classes of chemical residue. A laboratory may hold more than one accreditation.

AOAC methods—Methods of chemical analysis, Chapter 39, Association of Official Analytical Chemists (AOAC), published in the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990.[1] The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Chemical residue misidentification— see ''correct chemical residue identification'' definition.

Coefficient of variation (CV)— The standard deviation of a distribution of analytical values multiplied by 100, and divided by the mean of those values.

Comparison Mean—The average, for a sample, of all accredited and FSIS laboratories' average results, each of which has a large deviation measure of zero, except when only two laboratories perform the analysis, as in the case of split sample analysis by both an accredited laboratory and an FSIS laboratory. In the latter case, the comparison mean is the average of the two laboratories' results. For food chemistry, a result for a laboratory is the obtained analytical value; for chemical residues, a result is the logarithmic transformation of the obtained analytical value.

Correct chemical residue identification—Correct identification by a laboratory of a chemical residue whose concentration, in a sample, is equal to or greater than the minimum reporting level for that residue, as determined by the median of all positive analytical values obtained by laboratories analyzing the sample. Failure of a laboratory to report the presence such a chemical residue is considered a misidentification. In addition, reporting the presence of a residue at a level equal to or above the minimum reporting level that is not reported by 90 percent or more of all other laboratories analyzing the sample, is considered a misidentification.

CUSUM—A class of statistical procedures for assessing whether or not a

[1] A copy of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

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 four CUSUM procedures are:

(1) Positive systemic 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 discrepancy'' (i.e., the combination of the random fluctuations and systematic differences) between an accredited laboratory's results and the comparison mean;

(4) Individual large discrepancy CUSUM (CUSUM–D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

Individual large deviation—An analytical result from a non-Federal laboratory that differs from the sample comparison mean by more than would be expected assuming normal laboratory variability.

Initial accreditation check sample—A sample prepared and sent by an FSIS laboratory to a non-Federal laboratory to ascertain if the non-Federal laboratory's analytical capability meets the standards for granting accreditation.

Interlaboratory accreditation maintenance check sample—A sample prepared and sent by FSIS to a non-Federal laboratory to assist in determining if acceptable levels of analytical capability are being maintained by the accredited laboratory.

Large deviation measure—A measure that quantifies an unacceptably large difference between a non-Federal laboratory's analytical result and the sample comparison mean.

Minimum proficiency level—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. (See Table 2)

Minimum reporting level—The number such that if any obtained analytical value equals or exceeds this number, then the residue is reported together with the obtained analytical value.

Official Sample—A sample selected by a Program employee in accordance with FSIS procedures for regulatory use.

Probation— The period commencing with official notification to an accredited laboratory that its check or split sample results no longer satisfy the performance requirements specified in this rule, and ending with official notification that accreditation is either fully restored, suspended, or revoked.

QA (quality assurance) recovery—The ratio of a laboratory's unadjusted analytical value of a check sample residue to the residue level fortified by the FSIS laboratory that prepared the sample, multiplied by 100. (See Table 2.)

QC (quality control) recovery—The ratio of a laboratory's unadjusted analytical value of a quality control standard to the fortification level of the standard, multiplied by 100. (See Table 2.)

Refusal of Accreditation—An action taken when a laboratory which is applying for accreditation is denied the accreditation.

Responsibly connected—Any individual who or entity which is a partner, officer, director, manager, or owner of 10 per centum 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.

Revocation of Accreditation—An action taken against a laboratory which removes its right to analyze official samples.

Split sample— An official sample divided into duplicate portions, one portion to be analyzed by an accredited

laboratory (for official regulatory purposes) and the other portion by an FSIS laboratory (for comparison purposes).

Standardizing Constant—The number which is the result of a mathematical adjustment to the ''standardized value.'' Specifically, the number equals the square root of the expected variance of the difference between the accredited or applying laboratory's result and the comparison mean on a sample, taking into consideration the standardizing value, the correlation and number of repeated results by a laboratory on a sample, and the number of laboratories that analyzed the sample.

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.

Standardizing Value—A number representing the performance standard deviation of an individual result (see Tables 1 and 2 and footnotes to the Tables for determining exact procedures for calculation).

Suspension of Accreditation—Action taken against a laboratory which temporarily removes its right to analyze official samples. Suspension of accreditation ends when accreditation is either fully restored or revoked.

Systematic laboratory difference—A comparison of one laboratory's results with the comparison means on samples that shows, 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 and, conversely, numerically smaller results indicate a negative systematic laboratory difference.

Variability— Random fluctuations in a laboratory's processes that cause its analytical results to deviate from a true value.

Variance—The expected average of the squared differences of sample results from an expected sample mean.

TABLE 1.—STANDARDIZING VALUES FOR FOOD CHEMISTRY

[By product class and analyte]

Product/ Class	Moisture	Protein [1]	Fat [2]	Salt [3]
Cured Pork/ Canned Ham ..	0.50	0.060	0.26 (0.30)	0.127
Ground Beef ..	0.71	0.060	(0.35)	0.127
Other	0.57	0.060	0.26 (0.30)	0.127

[1] To obtain the standardizing value for a sample the appropriate entry in this column is multiplied by $X^{0.65}$ where X is the comparison mean of the sample.

[2] To obtain the standardizing value for a sample, the appropriate entry in this column is multiplied by $X^{0.25}$, where X is the comparison mean of the sample. The appropriate entry is equal to the value in parentheses when X is equal to or greater than 12.5 percent, otherwise it is equal to 0.26.

[3] To obtain the standardizing value for a sample, when the comparison mean of the sample, X, is less than 1.0 percent, the standardizing value equals 0.127, otherwise the appropriate entry is multiplied by $X^{0.25}$. When X is equal to or greater than 4.0 percent for dry salami and pepperoni products, the standardizing value equals 0.22.

TABLE 2.—MINIMUM PROFICIENCY LEVELS, PERCENT EXPECTED RECOVERIES (QC AND QA), AND STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Minimum proficiency level	Percent expected recovery (QC and QA)	Standardizing value [3]
Chlorinated Hydrocarbons:[1]			
Aldrin	0.10 ppm	80–110	0.20
Benzene Hexachloride	0.10 ppm	80–110	0.20
Chlordane	0.30 ppm	80–110	0.20
Dieldrin	0.10 ppm	80–110	0.20
DDT	0.15 ppm	80–110	0.20
DDE	0.10 ppm	80–110	0.20
TDE	0.15 ppm	80–110	0.20
Endrin	0.10 ppm	80–110	0.20
Heptachlor	0.10 ppm	80–110	0.20
Heptachlor Epoxide	0.10 ppm	80–110	0.20
Lindane	0.10 ppm	80–110	0.20
Methoxychlor	0.50 ppm	80–110	0.20
Toxaphene	1.00 ppm	80–110	0.20
Hexachlorobenzene	0.10 ppm	80–110	0.20
Mirex	0.10 ppm	80–110	0.20
Nonachlor	0.15 ppm	80–110	0.20
Polychlorinated Biphenyls:	0.50 ppm	80–110	0.20
Arsenic [2]	0.20 ppm	90–105	0.25
Sulfonamides [2]	0.08 ppm	70–120	0.25

TABLE 2.—MINIMUM PROFICIENCY LEVELS, PERCENT EXPECTED RECOVERIES (QC AND QA), AND STANDARDIZING VALUES FOR CHEMICAL RESIDUES—Continued

Class of residues	Minimum proficiency level	Percent expected recovery (QC and QA)	Standardizing value [3]
Volatile Nitrosamine [2]	5 ppm	70–110	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.

(b) *Laboratories accredited for analysis of protein, moisture, fat, and salt content of meat and meat products*—

(1) *Applying for accreditation.* Application for accreditation shall be made on designated forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory and sent to the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street SW., Washington, DC 20250–3700, and 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.

(i) At the time that an Application for Accreditation is filed with the Accredited Laboratory Program, FSIS, and annually thereafter upon receipt of the bill issued by FSIS on the anniversary date of each accreditation, the management of a laboratory shall reimburse the program at the rate specified in 9 CFR 391.5 for the cost of each accreditation that is sought for the laboratory or that the laboratory holds.

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward 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) sought by the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

(iii) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5.

(iv) 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. Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the Accredited Laboratory Program are paid.

(v) The accreditation of a laboratory that was accredited by FSIS on or before December 13, 1993 and was not on probation and whose accreditation on that date was not in suspension or revocation shall be continued, provided that such laboratory reapply for accreditation in accordance with the provisions of this paragraph (b)(1) by January 12, 1994 (30 days after the effective date of this section), and that the reapplication be accepted by the Agency. The CUSUM values for such laboratory will be reset at zero upon acceptance of its reapplication. The accreditation of a laboratory that is on probation shall be continued, provided that the laboratory reapply for accreditation by February 11, 1994 (60 days after the effective date of this section), that the reapplication be accepted by the Agency, and that the laboratory satisfy the terms of the probation.

(2) *Criteria for obtaining accreditation.* Non-Federal analytical laboratories may be accredited for the analyses of moisture, protein, fat, and salt content

of meat and meat food products. Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below, for all four analytes. This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples. To obtain FSIS accreditation for moisture, protein, fat, and salt analyses, a non-Federal analytical laboratory must:

(i) Be supervised by a person holding, as a minimum, a bachelor's degree in either chemistry, food science, food technology, or a related field and having 1 year's experience in food chemistry, or equivalent qualifications, as determined by the Administrator.

(ii) Demonstrate acceptable levels of systematic laboratory difference, variability, and individual large deviations in the analyses of moisture, protein, fat, and salt content using AOC methods. An applying laboratory will successfully demonstrate these capabilities if its moisture, protein, fat, and salt results from a 36 check sample accreditation study each satisfy the criteria presented below.[2] If the laboratory's analysis of an analyte (or analytes) from the first set of 36 check samples does not meet the criteria for obtaining accreditation, a second set of 36 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 samples shall be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory. If the results of the second set of samples do not meet the accreditation criteria, 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.

(A) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed 0.73 minus the product of 0.17 and the standard deviation of the standardized differences.

(B) *Variability:* The estimated standard deviation of the standardized differences must not exceed 1.15.

(C) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual samples must be less than 5.0.[3]

(iii) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

(iv) Pay the accreditation fee by the date required.

(3) *Criteria for maintaining accreditation.* To maintain accreditation for moisture, protein, fat, and salt analyses, a non-Federal analytical laboratory must:

(i) Report analytical results of the moisture, protein, fat, and salt content of official samples, weekly, on designated forms to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Quality Systems Branch, FSIS Chemistry Division.

(ii) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(iii) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under this Program.

(iv) Maintain a standards book, which is a permanently bound book with sequentially numbered pages, containing all readings and calculations for standardization of solutions, determination of recoveries, and calibration of instruments. All entries are to be dated and signed by the analyst immediately upon completion of the entry and by his/her supervisor within 2 working days. The standards book is to be retained for a period of 3 years after the last entry is made.

(v) Analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3

[2] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

[3] 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 $1–(2.5/d)^4$.

weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(vi) Inform the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., Washington, DC 20250–3700, by certified or registered mail, within 30 days, when there is any change in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(vii) Permit any duly authorized representative of the Secretary to perform both announced and unannounced onsite laboratory reviews of facilities and records during normal business hours, and to copy any records pertaining to the laboratory's participation in the Accredited Laboratory Program.

(viii) Use official AOAC methods[4] on official and check samples. The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(ix) Demonstrate that acceptable limits of systematic laboratory difference, variability, and individual large deviations are being maintained in the analyses of moisture, protein, fat, and salt content. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its moisture, protein, fat, and salt results from interlaboratory accreditation maintenance check samples and/or split samples satisfy the criteria presented below.[5]

(A) *Systematic laboratory difference:*

(*1*) *Positive systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–P. This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to:

2.0, if the standardized difference is greater than 1.6,
−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.

(*ii*) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding algebraically, the CUSUM 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. [CUSUM–P values are initialized at zero; that is, the CUSUM–P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed 5.2.

(*2*) *Negative systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–N. This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(*ii*) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically,

[4] A copy of the ''Official Methods of Analysis of the Association of Analytical Chemists,'' 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

[5] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

the CUSUM increment to 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. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed 5.2.

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split sample or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V. This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 and 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.

(*2*) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM 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. [CUSUM–V values are initialized at zero; that is, the CUSUM–V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(C) *Large deviations:* The large deviation measure of the accredited laboratory's result for each split sample or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.[6] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(*2*) Compute the new CUSUM–D value. The new CUSUM–D value is obtained by adding, algebraically, the CUSUM increment to the last previously computed CUSUM–D value. If this computation yields a value less that 0, the new CUSUM–D value is set equal to 0. [CUSUM–D values are initialized at zero; that is, the CUSUM–D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(x) Meet the following requirements if placed on probation pursuant to paragraph (e) of this section:

(A) 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, to an accredited laboratory approved for food chemistry. Mailing expenses will be paid by FSIS.

(B) Analyze a set of check samples similar to those used for initial accreditation, and submit the analytical results to FSIS within 3 weeks of receipt of the samples.

(C) Satisfy criteria for check samples specified in paragraphs (b)(2)(ii) (A), (B), and (C) of this section.

(xi) Expeditiously report analytical results of official samples to the FSIS Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Quality Systems Branch, FSIS Chemistry Division. 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.

(xii) Pay the required accreditation fee when it is due.

(c) *Laboratories accredited for analysis of a class of chemical residues in meat and meat food products.*

(1) *Applying for accreditation.* Application for accreditation shall be made on designated forms provided by FSIS, or otherwise in writing, by the owner or manager of the non-Federal analytical laboratory and sent to the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of

[6] *See* footnote 3.

Agriculture, 300 12th Street, SW., Washington, DC 20250–3700, and 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.

(i) At the time that an Application for Accreditation is filed with the Accredited Laboratory Program, FSIS, and annually thereafter upon receipt of the bill issued by FSIS on the anniversary date of each accreditation, the management of a laboratory shall reimburse the program at the rate specified in 9 CFR 391.5 for the cost of each accreditation that is sought for the laboratory or that the laboratory holds.

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward 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) sought for the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

(iii) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5.

(iv) 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. Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the Accredited Laboratory Program are paid.

(v) The accreditation of a laboratory that was accredited by FSIS on or before December 13, 1993 and was not on probation and whose accreditation on that date was not in suspension or revocation shall be continued, provided that such laboratory reapply for accreditation in accordance with the provisions of this paragraph (c)(1), by January 12, 1994 (30 days of the effective date of this section), and that the reapplication be accepted by the Agency. The CUSUM values for such laboratory will be reset at zero upon acceptance of its reapplication. The accreditation of a laboratory that is on probation shall be continued, provided that such laboratory reapply for accreditation by February 11, 1994 (60 days of the effective date of this section), that the reapplication be accepted by the Agency, and that the laboratory satisfy the terms of the probation.

(2) *Criteria for obtaining accreditation.* Non-Federal analytical laboratories may be accredited for the analysis of a class of chemical residues in meat and meat food products. Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below. This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples. To obtain FSIS accreditation for the analysis of a class of chemical residues, a non-Federal analytical laboratory must:

(i) Be supervised by a person holding, as a minimum, a bachelor's degree in either chemistry, food science, food technology, or a related field. Further, either the supervisor or the analyst assigned to analyze the sample must have 3 years' experience determining analytes at or below part per million levels, or equivalent qualifications, as determined by the Administrator.

(ii) Demonstrate acceptable limits of systematic laboratory difference, variability, individual large deviations, recoveries, and proper identification in the analysis of the class of chemical residues for which application was made, using FSIS approved procedures. An applying laboratory will successfully demonstrate these capabilities if its analytical results for each specific chemical residue provided in a check sample accreditation study containing a minimum of 14 samples satisfy the criteria presented in this paragraph

(c)(2)(ii).[7] 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 (c)(2)(ii)(A), (B), (C), (D), (E), and (F) 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.] If the results of the first set of check samples do not meet these criteria for obtaining accreditation, a second set of at least 14 samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. If the results of the second set of samples do not meet accreditation criteria, 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.

(A) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed 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.

(B) *Variability:* The standard deviation of the standardized differences must not exceed a computed limit. This limit is a function of the number of analytical results used in the computation of the standard deviation, and of the amount of variability associated with the results from the participating FSIS laboratories.

(C) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual analytical results must be less than 5.0.[8]

(D) *QA recovery:* The average of the QA recoveries of the individual analytical results must lie within the range given in Table 2 under the column entitled ''Percent Expected Recovery.''

(E) *QC recovery:* All QC recoveries must lie within the range given in Table 2 under ''Percent Expected Recovery.'' Supporting documentation must be made available to FSIS upon request.

(F) *Correct identification:* There must be correct identification of all chemical residues in all samples.

(iii) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

(iv) Pay the accreditation fee by the date required.

(3) *Criteria for maintaining accreditation.* To maintain accreditation for analysis of a class of chemical residues, a non-Federal analytical laboratory must:

(i) [Reserved]

(ii) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(iii) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under the Program.

(iv) Maintain a standards book, which is a permanently bound book with sequentially numbered pages, containing all readings and calculations for standardization of solutions, determination of recoveries, and calibration of instruments. All entries are to be dated and signed by the analyst immediately upon completion of the entry and by his/her supervisor within 2 working days. The standards book is to be retained for a period of 3 years after the last entry is made.

(v) Analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3 weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(vi) Inform the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street, SW., Washington, DC 20250–3700, by certified or registered mail, within 30 days of any change in the laboratory's ownership,

[7] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

[8] 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 $1–(2.5/d)^4$.

officers, directors, supervisory personnel, or any other responsibly connected individual or entity.

(vii) Permit any duly authorized representative of the Secretary to perform both announced and unannounced onsite laboratory reviews of facilities and records during normal business hours, and to copy any records pertaining to the laboratory's participation in the Accredited Laboratory Program.

(viii) Use analytical procedures designated and approved by FSIS.

(ix) Demonstrate that acceptable limits of systematic laboratory difference, variability, and individual large deviations are being maintained in the analysis of samples, in the chemical residue class for which accreditation was granted. A laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results for each specific chemical residue found in interlaboratory accreditation maintenance check samples and/or split samples satisfy the criteria presented in this paragraph (c)(3)(ix).[9,10] In addition, if the laboratory is accredited for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria.

(A) *Systematic laboratory difference:*

(*1*) *Positive systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–P.[11] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(*ii*) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM 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. [CUSUM–P values are initialized at zero; that is, the CUSUM–P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed 4.8.

(*2*) *Negative systematic laboratory difference:* The standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–N.[12] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(*ii*) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically,

[9] All statistical computations are rounded to the nearest tenth, except where otherwise noted.

[10] An analytical result will only be used in the statistical evaluation of the laboratory if the associated comparison mean is equal to or greater than the logarithm of the minimum proficiency level for the residue.

[11] 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.

[12] *See* footnote 11.

the CUSUM increment to 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. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed 4.8.

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and that of the FSIS laboratory for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.[13] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 and 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.

(*2*) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM 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. [CUSUM–V values are initialized at zero; that is, the CUSUM–V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(C) *Large Deviations:* The large deviation measure of the accredited laboratory's result for each split and/or interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.[14] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the large deviation measure minus 0.025.

(*2*) Compute the new CUSUM–D value. The new CUSUM–D is obtained by adding, algebraically, the CUSUM 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. [CUSUM–D values are initialized at zero; that is, the CUSUM–D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(x) Meet the following requirements if placed on probation pursuant to paragraph (e) of this section:

(A) 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, to an accredited laboratory accredited for this specific chemical residue. Mailing expense will be paid by FSIS.

(B) Analyze a set of check samples similar to those used for initial accreditation, and submit analytical results to FSIS within 3 weeks of receipt of the samples.

(C) Satisfy criteria for check samples as specified in paragraphs (c)(2)(ii) (A), (B), (C), (D), (E), and (F) of this section.

(xi) Expeditiously report analytical results of official samples to the Eastern Laboratory, College Station Road, P.O. Box 6085, Athens, GA 30604, or to the address designated by the Quality Systems Branch, FSIS Chemistry Division. The Federal inspector at any establishment may assign the analysis of official samples to an FSIS laboratory if, in the judgment of the inspector,

[13] 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.

[14] 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 $1-(2.5/d)^4$.

there are delays in receiving test results on official samples from an accredited laboratory.

(xii) Every QC recovery associated with reporting of official samples must be within the appropriate range given in Table 2 under ''Percent Expected Recovery.'' Supporting documentation must be made available to FSIS upon request.

(xiii) Demonstrate that acceptable levels of systematic laboratory difference, variability, individual large deviations, recoveries, and proper identification are being maintained in the analysis of interlaboratory accreditation maintenance check samples, in the chemical residue class for which accreditation was granted. A laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results for each specific chemical residue found in interlaboratory accreditation maintenance check samples satisfy the criteria presented below. In addition, if the laboratory is accredited for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria.

(A) *Systematic laboratory difference—*(*1*) *Positive 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 a CUSUM value, designated as CUSUM–P.[15] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(*ii*) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM 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. [CUSUM–P values are initialized at zero; that is, the CUSUM–P value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed 4.8.

(*2*) *Negative 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 a CUSUM value, designated as CUSUM–N.[16] This value is computed and evaluated as follows:

(*i*) Determine the CUSUM increment for the sample. The CUSUM increment 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.

(*ii*) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM increment to 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. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*iii*) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed 4.8.

(B) *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.[17] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 or the

[15] *See* footnote 11.

[16] *See* footnote 11.

[17] *See* footnote 13.

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.

(*2*) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM 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. [CUSUM–V values are initialized at zero; that is, the CUSUM–V value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(C) *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.[18] This value is computed and evaluated as follows:

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(*2*) Compute the new CUSUM–D value. The new CUSUM–D is obtained by adding, algebraically, the CUSUM 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. [CUSUM–D values are initialized at zero; that is, the CUSUM–D value associated with the first sample is set equal to the CUSUM increment for that sample.]

(*3*) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(D) Each QC Recovery is within the range given in Table 2 under ''Percent Expected Recovery''. Supporting documentation must be made available to FSIS upon request.

(E) Not more than 1 residue misidentification in any 2 consecutive check samples.

(F) Not more than 2 residue misidentifications in any 8 consecutive check samples.

(xiv) Pay the accreditation fee when it is due.

(d) *Refusal of accreditation.* Upon a determination by the Administrator, a laboratory shall be refused accreditation for the following reasons:

(1) A laboratory shall be refused accreditation for moisture, protein, fat, and salt analysis for failure to meet the requirements of paragraph (b)(1) or (b)(2) of this section.

(2) A laboratory shall be refused accreditation for chemical residue analysis for failure to meet the requirements of paragraph (c)(1) or (c)(2) of this section.

(3) A laboratory shall be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, all official samples which have not been analyzed as of the notification of a loss of accreditation.

(4) A laboratory shall be refused accreditation if the applicant or any individual or entity responsibly connected with the applicant has been convicted of or is under indictment or if charges on an information have been brought against the applicant or responsibly connected individual or entity in any Federal or State court concerning the following violations of law:

(i) Any felony.

(ii) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(iii) Any misdemeanor based upon a false statement to any governmental agency.

(iv) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

(e) *Probation of accreditation.* Upon a determination by the Administrator, a laboratory shall be placed on probation for the following reasons:

(1) If the laboratory fails to complete more than one interlaboratory accreditation maintenance check sample analysis within 12 consecutive months as required by paragraphs (b)(3)(v) and (c)(3)(v) of this section.

[18] 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 $1-(2.5/d)^4$.

(2) If the laboratory fails to meet any of the criteria set forth in paragraphs (b)(3)(v) and ((b)(3)(ix) and (c)(3)(v) and (c)(3)(ix) of this section.

(f) *Suspension of accreditation.* The accreditation of a laboratory shall be suspended if the laboratory or any individual or entity responsibly connected with the laboratory is indicted or if charges on an information have been brought against the laboratory or responsibly connected individual or entity in any 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.

(g) *Revocation of accreditation.* The accreditation of a laboratory shall be revoked for the following reasons:

(1) An accredited laboratory which is accredited to perform analysis under paragraph (b) of this section shall have its accreditation revoked for failure to meet any of the requirements of paragraph (b)(3) of this section except for the following circumstances. If the accredited laboratory fails to meet the criteria for reporting the analytical results on interlaboratory accreditation maintenance check samples as set forth in paragraph (b)(3)(v) of this section or if, at any time, the CUSUM results from the analysis of such interlaboratory accreditation maintenance check samples and/or split samples have not satisfied the criteria specified in paragraph (b)(3)(ix) of this section and there have been, during the previous 12 months, no other occasions on which such CUSUM results have not satisfied such criteria, the laboratory shall be placed on probation; but if there have been such other occasions during those 12 months, the laboratory's accreditation will be revoked.

(2) An accredited laboratory which is accredited to perform analysis for a class of chemical residues under paragraph (c) of this section shall have the accreditation to perform this analysis revoked if it fails to meet any of the requirements in paragraph (c)(3) of this section except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in paragraphs (c)(3)(v), (c)(3)(ix), and (c)(3)(xiii) of this section and it has not so failed during the 12 months preceding its failure to meet the criteria, it shall be placed on probation, but if it has so failed at any time during those 12 months, its accreditation will be revoked.

(3) An accredited laboratory shall have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(i) Altered any official sample or analytical finding, or,

(ii) Substituted any analytical result from any other laboratory for its own.

(4) An accredited laboratory shall 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:

(i) Any felony.

(ii) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(iii) Any misdemeanor based upon a false statement to any governmental agency.

(iv) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

(h) *Notification and hearings.* Accreditation of any laboratory shall be refused, suspended, or revoked under the conditions previously described herein. The owner or operator of the laboratory shall 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 shall be granted if there is any dispute of material fact joined in such responsive statement. The proceeding shall thereafter be conducted in accordance with the applicable rules of practice which shall be adopted for the proceeding. Any such refusal, suspension, or revocation shall be effective upon the receipt by the laboratory of the notification and shall continue in effect until final determination of the matter by the Administrator.

(Reporting and recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0015)

[52 FR 2185, Jan. 20, 1987, as amended at 58 FR 65260, 65262–65264, Dec. 13, 1993; 59 FR 33642, June 30, 1994; 59 FR 66448, Dec. 27, 1994; 60 FR 10305, Feb. 24, 1995]

§318.22 Determination of added water in cooked sausages.

(a) For purposes of this section, the following definitions apply.

(1) *Cooked sausage.* Cooked sausage is any product described in §319.140 and §§319.180–319.182 of this chapter.

(2) *Group 1 Protein-Contributing Ingredients.* Ingredients of livestock or poultry origin from muscle tissue which is skeletal or which is found in the edible organs, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing; meat byproducts; mechanically separated (species); and poultry products; except those ingredients processed by hydrolysis, extraction, concentrating or drying.

(3) *Group 2 Protein-Contributing Ingredients.* Ingredients from Gorup 1 protein-contributing ingredients processed by hydrolysis, extraction, concentrating, or drying, or any other ingredient which contributes protein.

(b) The amount of added water in cooked sausage is calculated by:

(1) Determining by laboratory analysis the total percentage of water contained in the cooked sausage; and

(2) Determining by laboratory analysis the total percentage of protein contained in the cooked sausage; and

(3) Calculating the percentage of protein in the cooked sausage contributed by the Group 2 protein-contributing ingredients; and

(4) Subtracting one pecent from the total percentage of protein calculated in (b)(3)); and

(5) Subtracting the remaining percentage of protein calculated in (b)(3) from the total protein content determined in (b)(2); and

(6) Calculating the percentage of indigenous water in the cooked sausage by multiplying the percentage of protein determined in (b)(5) by 4, (This amount is the percentage of water attributable to Group 1 protein-contributing ingredients and one percent of Group 2 protein-contributing ingredients in a cooked sausage.); and

(7) Subtracting the percentage of water calculated in (b)(6) from the total percentage of water determined in (b)(1). (This amount is the percentage of added water in a cooked sausage.)[1]

[55 FR 7299, Mar. 1, 1990]

§318.23 Heat-processing procedures, cooking instructions, and cooling, handling, and storage requirements for uncured meat patties.

(a) *Definitions.* For purposes of this section, the following definitions shall apply:

(1) *Comminuted.* A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.

(2) *Heat-processed.* Treatment by a heat source, including, but not limited to, frying, broiling, baking, or roasting, which results in a fully-cooked, partially-cooked, or char-marked product.

(3) *Patty.* A shaped and formed, comminuted, flattened cake of meat food product.

[1] The equation for the narrative description of the calculation for added water is as follows: AW=TW-(TP-(P-1.0))4, Where AW=Added Water, TW-Total Water Determined by Laboratory Analysis, TP=Total Protein Determined by Laboratory Analysis, P=Protein Contributed by Group 2 Protein-Contributing Ingredients, 1.0=Percent Allowance for Group 2 Protein-Contributing Ingredients, 4=Moisture-Protein Ratio for Cooked Sausage.

(b) *Processing procedures for heat-processed patties.* Fully-cooked, partially-cooked, or char-marked patties shall be processed as follows:

(1) *Heat processing.* (i) Official establishments which manufacture fully-cooked patties shall utilize one of the heat-processing procedures in Table A of this paragraph:

TABLE A.—PERMITTED HEAT-PROCESSING TEMPERATURE/TIME COMBINATIONS FOR FULLY-COOKED PATTIES

Minimum internal temperature at the center of each patty		Minimum holding time after maximum temperature is reached	
Degrees		Time	
Fahrenheit	or Centigrade	(Minutes)	or (Seconds)
151	66.1	0.68	41
152	66.7	.54	32
153	67.2	.43	26
154	67.8	.34	20
155	68.3	.27	16
156	68.9	.22	13
157 (and up)	69.4 (and up)	.17	10

(ii) Official establishments which manufacture partially-cooked patties shall raise the internal temperature at the center of each patty to a minimum internal temperature of 140 °F. and then cool it to a maximum internal temperature of 40 °F within 2 hours.

(iii) Official establishments which manufacture char-marked patties (if marked by a heat source) may raise the temperature at the center of each patty, but not above 70 °F, when the char-marks are applied to the patty. The process of char-marking the patty and cooling the patty to a maximum internal temperature of 40 °F shall be completed within 2 hours or less.

(iv) The official establishment shall measure the holding time and temperature of at least one heat-processed patty from each production line each hour of production to assure control of the heat process. The temperature measuring device shall be accurate within 1 °F.

(2) *Cooling.* (i) Fully-cooked patties shall be cooled to an internal temperature of 40 °F or below within 2 hours after heat-processing.

(ii) Cooling requirements for partially-cooked and char-marked patties are combined with those for heat-processing and are contained in paragraph (b)(1)(ii) and (iii) of this section.

(iii) The internal temperature measuring device shall be accurate within 1 °F.

(3) *Cooking instruction label requirement.* (i) Partially-cooked patties shall bear the labeling statement ''Partially-cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 °F)''. The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) Char-marked patties. Product shall bear the labeling statement ''Uncooked, Char-marked: For Safety, Cook Until Well Done (Internal Meat Temperature 160 °F)''. The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) *Sanitary handling and storage practices.* Fully-cooked patties shall be handled in accordance with the following provisions so as to assure that the patties are not recontaminated.

(i) To prevent direct contamination of fully-cooked patties, official establishments shall:

(A) Physically separate areas where unpackaged, fully-cooked patties are handled from areas where less-than-fully-cooked products are handled using a solid impervious floor to ceiling wall; or

(B) Handle unpackaged, fully-cooked patties and less-than-fully-cooked product at different times, and cleaning the entire area after handling other products before handling unpackaged, fully-cooked patties; or

(C) Submit a written procedure through the inspector-in-charge to the Regional Director detailing the steps

to be taken which would avoid recontamination of fully-cooked patties by less-than-fully-cooked cooked product during processing.

(ii) To prevent indirect contamination of fully-cooked patties:

(A) Any work surface, machine, or tool which contacts other product shall be cleaned and sanitized before it contacts unpackaged fully-cooked patties. The sanitizer shall be germicidally equivalent to 50 ppm chlorine.

(B) Employees shall wash their hands with soap and water and sanitize their hands whenever they enter the fully-cooked patty area or before handling unpackaged, fully-cooked patties. They must also wash and sanitize their hands whenever they become contaminated during operations to avoid contamination of fully-cooked patties. The sanitizer shall be germicidally equivalent to 50 ppm chlorine.

(C) All employee outer garments, including aprons, smocks, and gloves shall be identified as restricted for use in the fully-cooked area only. The employee shall change garments at least daily. The garments shall be hung in a designated location before the employee leaves the area.

(iii) Fully-cooked patties stored in the same room with other product, shall first be packaged or covered to prevent microbial contamination.

(iv) Fully-cooked, partially-cooked, and char-marked patties shall be stored at a chamber temperature of 40 °F or below.

(c) *Requirements for handling heating or cooling deviations.* (1) If for any reason a heating or cooling deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized representative of the Secretary, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence; and

(2) In addition, in the case of a heating deviation, the official establishment may (i) reprocess the affected product, by a method in paragraph (b)(1)(i) in this section, or (ii) use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (b)(1)(i) in this section, provided this does not violate the final product's standard of composition, upset the order of predominance of ingredients, or perceptibly affect the normal product characteristics, or (iii) relabel the affected product as a partially-cooked patty product, if it meets the partially-cooked requirements in paragraph (b)(1)(ii) of this section.

(3) In addition, in the case of a cooling deviation, contact the Regional Director to determine the disposition of the product.

[58 FR 41151, Aug. 2, 1993]

§318.24 Compliance procedures for meat derived from advanced meat/bone separation machinery and recovery systems.

(a) The product resulting from the separating process shall not have a calcium content exceeding 0.15 percent or 150 mg/100 gm of product within a tolerance of 0.03 percent or 30 mg, as prescribed in §301.2(rr)(2) of this subchapter.

(b) To verify the calcium content in meat derived from advanced meat/bone separation machinery and recovery systems, a compliance program consisting of the following parameters shall be followed by manufacturers of meat defined in §301.2(rr)(2) of this subchapter.

(1) An analysis of a sample of at least 1 pound from each lot shall be performed by the operator of the establishment or his or her agent. For purposes of this paragraph, a lot shall consist of the meat derived from advanced meat/bone separation machinery and recovery systems, designated as such by the operator of the establishment or his or her agent, from the product produced from a single species of livestock in no more than one continuous shift of up to 12 hours. Individual results from the chemical analyses shall be compared to the calcium limit, prescribed in paragraph (a) of this section, in order to demonstrate compliance. If compliance is not demonstrated, that is, if any single analytical result is

more than 0.18 percent,[1] [2] before product from a production lot that is still at the establishment or one that is subsequently produced can be considered to be in compliance, at least three samples from that production lot shall be taken and analyzed for calcium, either separately, or, at the option of the establishment, as a composite (i.e., combining the three samples for analysis). The average of the results or the composite result must be less than or equal to 0.15 percent. Taking three samples from each subsequently produced lot and analyzing them in order to demonstrate compliance shall continue until five consecutive lots have mean or composite results less than or equal to 0.15 percent. If the statistical evidence indicates that a production lot is not in compliance with the calcium limit, as prescribed in §301.2(rr)(2) of this subchapter, the lot must be labeled as MS(S) and meet all of the requirements for MS(S) in §319.5 of this subchapter.

(2) The management of the establishment must maintain records to support the validity of the calcium content (as a measure of bone solids) to assure the process is in control. Such records shall be made available to the inspector or any other duly authorized representative of the Agency upon request. (Recordkeeping requirements were approved by the Office of Management and Budget under control number 0583–0095.)

[59 FR 62561, Dec. 6, 1994]

[1] The value 0.18 percent was derived by multiplying by 3 the expected analytical standard deviation obtained by FSIS laboratories on the approved chemical procedure for measuring calcium which uses Ethylenediaminetetraacetic acid (EDTA) as provided in the ''Official Methods of Analysis of the AOAC International'' (formerly the Association of Official Analytical Chemists), 15th Ed. (1990).

[2] Individual or an average of results shall be rounded to the nearest 0.01 percent calcium.

Subparts B—F [Reserved]

Subpart G—Canning and Canned Products

SOURCE: 51 FR 45619, Dec. 19, 1986, unless otherwise noted.

§318.300 Definitions.

(a) *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.

(b) *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.

(c) *Bleeders.* Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

(d) *Canned product.* A meat 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 subpart G shall mean ''canned product.''

(e) *Closure technician.* The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.

(f) *Code lot.* All production of a particular product in a specific size container marked with a specific container code.

(g) *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.